

CONFIDENTIAL

REPORT OF THE EXPERT GROUP

Under the Chairmanship of Dr. C.D. Mayee

For Pesticides Reviewed for their continued use or
otherwise in the country.

Part III

Submitted to
The Registration Committee

MINISTRY OF AGRICULTURE
DEPARTMENT OF AGRICULTURE AND COOPERATION

2007

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EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

The Registration Committee on the directives of the Inter-ministerial Committee constituted a group under the Chairmanship of Dr. C.D. Mayee, Chairman, Agricultural Scientists Recruitment Board (ASRB), Indian Council of Agricultural Research, Krishi Anusandhan Bhawan, Pusa, New Delhi to review toxicity, persistence, safety in use and substitute available of 36 pesticides and monocrotophos (List at Annexure I) and make recommendations for their continued use or otherwise in the country. The group undertook the review and has made the following specific recommendations w.r.t. pesticides reviewed in the Third phase.

1. Benfuracarb

Use of Benfuracarb be continued

2. Bifenthrin

- i. Use of Bifenthrin be continued
- ii. The label and leaflets should bear the safety precaution that it should not be used in the areas where pisciculture /aquaculture is practiced.

3. Chlorofenvinphos

The manufacture, import and use of Chlorofenvinphos may be banned.

4. Dazomet

- Use of Dazomet be continued on all registered crops except tea.

5. Diflubenzuron

Use of Diflubenzuron be continued.

6. Fenpropathrin

- i. Use of Fenpropathrin be continued.
- ii. The label and leaflets should bear the safety precaution that it should not be used in the areas where pisciculture /aquaculture is practiced.

7. Iprodione

Use of Iprodione be continued

8. Kasugamycin

Use of Kasugamycin be continued

9. Linuron

- At present label claim on potato & peas may be continued subject to review after five years or whenever label expansion is being sought.

10. Mepiquat Chloride

Use of Mepiquat Chloride be continued.

11. Propargite

Use of Propargite be continued.

12. Propineb

Use of Propineb be continued.

13. Thiodicarb

Use of Thiodicarb be continued.

14. Trichlorofon

Use of Trichlorofon be continued with following precautions:

- It should not be used near areas where aquaculture is practiced.
- Its use as seed dresser and late stage spray on crops should be avoided.

15. Simazine:

The product has been withdrawn vide Notification No. S.O 915(E) dated 15th June, 2006. The withdrawal made by the Government pursuant to this order shall become inoperative as soon as the required data for the insecticide (s) as per the guidelines is generated and submitted by the Pesticide Industry to the Government and accepted by the Registration Committee. Therefore, the Expert Group decided that the Registration Committee may review this pesticide from all angles as and when data are submitted by the pesticides Industry.

16. Dalapon:

The product has been withdrawn vide Notification No. S.O 915(E) dated 15th June, 2006. The withdrawal made by the Government pursuant to this order shall become inoperative as soon as the required data for the insecticide (s) as per the guidelines is generated and submitted by the Pesticide Industry to the Government and accepted by the Registration Committee. Therefore, the Expert Group decided that the Registration Committee may

review this pesticide from all angles as and when data are submitted by the pesticides Industry.

General Recommendations:

After a detailed discussion with the industry and among the members and based on the scientific information, the Group has given the following general recommendations.

1. No pesticide belonging to extremely toxic (Red triangle) category be registered unless it is extremely necessary and sufficient justification for the same is available.
2. Maximum Residue Limits (tolerance limits) for the pesticides be fixed for all pesticides which are in use in the country.
3. There is need to promote the concept of Good Agricultural Practices in use of pesticides.
4. The committee felt that the products which are banned/restricted in the countries where agriculture is not a predominant profession should not be considered as a criteria for consideration of review. Instead if a product is banned/restricted in a country which is agriculturally important and where agriculture is practiced as a livelihood security should be immediately considered for review in India.
5. The manufacturers should also carry out medical examination of workers in manufacturing facilities for specific ailments recommended based on animal toxicity data. Specific tests required for a particular pesticide e.g. thyroid function test for workers in Mancozeb manufacturing units etc. could be prescribed by the medical toxicologists/suggested by the Registration Committee. The mechanism for periodic review of health records by qualified Medical expert should be established.
6. The Committee felt that the studies for monitoring resistance to pest-pathogens need to be strengthened as the field use of some of the chemicals intensify.

PREAMBLE

PREAMBLE:**Background regarding the composition of the expert group**

In pursuance to the order of the Supreme Court in its judgment in the case of the writ petition No. 1094 of 1988 a Committee [Interministerial Committee (IMC)] has been constituted with the Secretary, Department of Agriculture & Cooperation as Chairman and Secretary, Department of Chemicals & Petrochemicals ; Secretary, Department of health and Secretary , Ministry of environment and forest as members to review the use of Insecticides and Chemicals found Hazardous to health and take suitable remedial measures in this regard. In the 25th meeting of IMC a list of pesticides which have been banned/ restricted in other countries but being used in India and the statement containing the review status of those pesticides was put up for deliberation. The Committee decided that the Registration Committee should take up the review of the remaining pesticides within a stipulated time frame. Based on the decision of Inter Ministerial Committee, the Government of India, Ministry of Agriculture (Department of Agriculture & Cooperation) decided to undertake review of 36 pesticides and monocrotophos(Annexure.I) through Registration Committee (RC) to consider their continued use or otherwise in the country. For the purpose, a Group was constituted by the RC in its 252nd – 253rd meeting under the Chairmanship of Dr. C.D. Mayee, Chairman, ASRB, Indian Council of Agricultural Research. The terms of reference for the group were laid down in the 254th meeting (copy at Annexure II)The constitution of the group is as under :

- | | |
|--|----------|
| 1. Dr. C.D. Mayee,
Chairman ASRB,
Indian Council of Agricultural Research Institute ,
Krishi Anusanshan bhavan-1 ,
PUSA, New Delhi | Chairman |
| 2. Dr P.S. Chandurkar
Plant Protection Adviser
to the Govt. of India,
Dte. of PPQ&S, Faridabad | Member |
| 3. Shri P.N. Maji,
Additional Industrial Advisor,
Representative from Deptt. of Chemicals
& Petro Chemicals, New Delhi. | Member |
| 4. Dr. O.P. Dubey
ADG(OP),
Indian Council of Agricultural research
Krishi Bhavan New Delhi | Member |
| 5. Dr. S. K. Handa
WHO Consultant
Room No 526 , Wing A
Representative from PFA Div.
Min. Of Health & Family Welfare,
New Delhi | Member |

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|-----|---|------------------|
| 6. | Dr. H.N. Salyed
Director, National Institute of Occupational Health(NIOH.)
Indian Council of Medical research
Ahmedabad- 380016 | Member |
| 7. | Dr. Y.K. Gupta
Professor & Head
Department of pharmacology
All India Institute of Medical Sciences
Ansari Nagar, New Delhi-110029 | Member |
| 8. | Dr. (Mrs.) Chanda Chaudhary
Addl. Director HSM Division,
Ministry of Environment & Forests
CGO Complex, Lodi road, New Delhi | Member |
| 9. | Dr. B.S. Parmer
Joint. Director (Research),
IARI, Pusa, New Delhi. | Member |
| 10. | Dr. R.A. Tripathi
Prof.& Head, Div. Member of
Entomology, CS Azad Unl. of
Agri.& Tech, Kanpur | Member |
| 11. | Dr. Y.S. Ahlawat
Division . of Plant Pathology,
IARI, New Delhi-12 | Member |
| 12. | Dr. L.S. Barar
Prof.& Head, Deptt. of Agronomy,
PAU, Ludhiana | Member |
| 13. | Dr. (Mrs.) Sandhya Kulshrestha,
Secretary CIB & RC
N. H. IV, Faridabad | Member Secretary |

The group Co-opted the following members :-

- | | | |
|----|---|-----------------|
| 1. | Dr. T. P. Rajendran
ADG (PP)
Indian Council of Agricultural research
Krishi Bhavan New Delhi, | Co-opted Member |
| 2. | Dr. A.K. Majumdar,
Director (IH),
Director (IH),
Central labour Institute, Sion, Mumbai 400 022. | Co-opted Member |

3. Dr. T.S Thind ,
Professor Plant Pathology,
Deptt. of Plant Pathology,
PAU, Ludhiana-141004 (Punjab) Co-opted Member
4. Dr. Keshav Kranti,
Senior Scientist, Entomology,
CICR, Post Bag No.2,
Nagpur-440010 (MS) Co-opted Member
5. Dr. N.T. Yaduraju,
National Coordinator,
National Agricultural Innovation Project
ICAR, Krishi Anusandhan Bhawan -II
Pusa Campus, New Delhi Co-opted Member
6. Dr. K.K. Sharma,
Project Coordinator,
AICRP on Pesticide Residue,
LBS Building, IARI,
New Delhi-110012 Co-opted Member

**MODALITIES FOR THE
FUNCTIONING OF THE
GROUP AND
PREPARATION OF THE
REPORT**

MODALITIES FOR THE FUNCTIONING OF THE GROUP AND PREPARATION OF THE REPORT

The list of pesticides reviewed in Third phase is as under :-

- 1) Benfuracarb
- 2) Bifenthrin
- 3) Chlorofenvinphos
- 4) Dazomet
- 5) Diflubenzuron
- 6) Fenpropathrin
- 7) Iprodione
- 8) Kasugamycin
- 9) Linuron
- 10) Mepiquat Chloride
- 11) Propargite
- 12) Propinab
- 13) Thiodicarb
- 14) Trichlorofon
- 15) Simazine:
- 16) Dalapon:

The group followed the same modalities i.e followed for review of pesticides in the first & Second phase. The group met four more times i.e 9th, 10th, 11th & 12th meeting of the committee which were held on 10th November, 2006, 14th December, 2006, 20th February, 2007 & 19th March, 2007 to discuss the pesticides under review in the Third phase. The Group reviewed the literature and prepared the base papers on each of the pesticides under review. The base papers were deliberated. After a detailed discussion with the industry and among the members and based on the scientific information, the Group has given certain general recommendations apart from specific recommendations.

PRODUCT SPECIFIC RECOMMENDATIONS

PRODUCT SPECIFIC RECOMMENDATIONS:

1) Benfuracarb

Benfuracarb is a carbamate insecticide and is moderately hazardous (Class II) as per WHO recommended Classification of Pesticides by Hazard 2004.

1.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is restricted in Korea because of high acute toxicity and being highly hazardous. Restricted for transportation, sale, storage, object of supply and use under the Agrochemical Management Act. Prohibited to rice plant.

1.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

1.2 (a) PESTICIDE CONSUMPTION IN INDIA

14,437 lit. (2005-06) & 74,690 lit. (2006-07) of Benfuracarb 40% EC
Source: Coromandel Fertilisers, Secunderabad

1.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Benfuracarb 3% GR & 40 EC – Rice & Redgram

1.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The committee noted that Benfuracarb is restricted in Korea because of its high acute toxicity and being highly hazardous. The industry clarified that Benfuracarb technical or its formulations are not banned or restricted in Korea or in any other country. It is imported from Japan by Dong Bang Agro. Corporation (copy of registration certificate submitted). Further, it is moderately hazardous (Class II) insecticide as per WHO recommended Classification of Pesticides by Hazard 2004 and many pesticides belonging to this category are in use in the country. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at **Annexure- III-A**). Considering the facts the group recommended the following:-

1.4 RECOMMENDATION:

Use of Benfuracarb be continued.

2) Bifenthrin

Bifenthrin is a Pyrethroid insecticide and is moderately hazardous (Class II) as per WHO recommended Classification of Pesticides by Hazard 2004.

2.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is restricted in Netherlands because of being extremely toxic to water organisms. Persistence in soil and water and bio-accumulation. Use restricted to glass houses-

cultures with minimized emission of effluents to the surface water. Use in the open field (orchards) are not allowed.

2.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

2.2 (a) PESTICIDE CONSUMPTION IN INDIA

Data not available. It is approved for use in the country in 2003

2.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Bifenthrin 2.5% EC, 10% EC & 10% WP - Coltron, Termite control in pre post construction in buildings & public health use.

2.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTANCE:

The group noted that Bifenthrin is moderately hazardous (Class II) insecticide as per WHO recommended Classification of Pesticides by Hazard 2004. It is restricted in the Netherlands being extremely toxic to water organisms. Persistence in Soil and water and bio-accumulation. Use restricted to glass houses-cultures with minimized emission of effluents to the surface water. Use in the open field (Orchards) are not allowed.

The committee noted the submission of the applicant that Bifenthrin has never been banned or restricted for use in the Netherlands and erstwhile (USSR). It further submitted that the entry for Netherlands in the UN consolidated List states that Bifenthrin use is restricted to glass houses and cannot be used in the open field (orchards). The wording of this entry derived from a registration application in the early 1990's by an FMC representative company, which sought approval for glass house uses, but then decided that the commercial opportunity at the time did not justify expenditure on the additional studies requested by the review authorities and withdrew the application. The authorities decided that the information available in the registration application at the time would support glass house use, but not open field uses. The Netherlands entry in the UN consolidated list reflects the Dutch authorities' interpretation of the registration status, which appears to be a severe regulatory action, but in fact is not. The original entry to the UN consolidated List from the USSR stated that Bifenthrin "is not approved for use as a pesticide" This is an outdated entry that was never updated to reflect an accurate status of Bifenthrin in the USSR. As they know, the USSR no longer exists as a governmental entity therefore, it is not possible for them to provide any authoritative evidence on Bifenthrin's status in that country as of today. Further, the committee noted that Bifenthrin was recently registered in 2003 after considering all these aspects including ban/restriction in other countries. Considering the fact that the product is toxic to aquatic organisms, the committee recommended the following:

2.4 RECOMMENDATIONS:

1. Use of Bifenthrin be continued
2. The label and leaflets should bear the safety precaution that it should not be used in the areas where pisciculture /aquaculture is practiced.

3) Chlorofenvinphos

Chlorofenvinphos is an Organo phosphorous insecticide and is highly hazardous (Class I B) technical grade active ingredient as per WHO recommended Classification of Pesticides by Hazard 2004.

3.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is restricted in Belize because of extreme toxicity. Severely restricted soil insecticide only.

3.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

3.2 (a) PESTICIDE CONSUMPTION IN INDIA

8 MT Technical grade (2003- 04)
(Source: States / UT's)

3.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Chlorofenvinphos 10 GR - Sugarcane, Banana, Turmeric, Ginger, Rice, Sorghum, Public health & for the control of cutworm, Whitegrub & Millipede on all crops.

3.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Chlorofenvinphos is highly hazardous (Class I B) technical grade active ingredient as per WHO recommended Classification of Pesticides by Hazard 2004. It is restricted in Belize because of extreme toxicity. Severely restricted soil insecticide only. The acute oral Rat LD 50 is 10 mg/kg b.w. The consumption is very low (8 M.T) and substitutes are available. Further, no industry has responded to address the concerns. Considering the facts the group recommended the following:

3.4 RECOMMENDATIONS:

The manufacture, import and use of Chlorofenvinphos may be banned.

4) Dazomet

Dazomet is a nematicide and is slightly hazardous (Class III) technical grade active ingredient as per WHO recommended Classification of Pesticides by Hazard 2004.

4.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is banned in Denmark because it has been assessed as a risk to cause ground water pollution and furthermore assessed to be harmful to the unborn child, in soil and if products are therefore assessed to be harmful to health and environment. Withdrawn from market since 31st Dec., 1996. No uses are allowed. For other categories than agriculture a written authorization has to be obtained.

4.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

4.2 (a) PESTICIDE CONSUMPTION IN INDIA

The product is registered in India in 2002.

1792 kg(2005-06); 3497 kg(2006-07)

Source: M/s Margo bio-controls Pvt. Ltd. Bangalore

4.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Dazomet Technical-Tobacco, Tomato, Tea & in Floriculture as soil fumigant for nematodes.

4.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that the product is banned in Denmark because it is assessed as a risk to cause ground water pollution and furthermore assessed to be harmful to the unborn child, in soil and the products are therefore assessed to be harmful to health and environment. The group noted the submission of the industry that the Danish authorities have granted registration of Basamid(Dazomet) vide No. J.nr.M 741-0174 Ref: Jep dated 14.02.2005, whereas in Europe, U.S.A and many countries in Asia, Dazomet was registered in 1980s and the product has been in use for more than 20 years without any problem. Nowhere in the world Dazomet is banned. It was true that the Danish authorities had planned for "restrict use of Dazomet" but due to overwhelming response from the users and growers in favour of Basamid the decision was withdrawn and permission was granted to continue with the sale of Dazomet in Denmark. The results of the outdoor lysimeter study demonstrate that after treatment with 2- C14 Dazomet, there is no substantial transport of the major metabolite MITC into deeper soil layer or into the groundwater. No adverse effects on reproduction parameters and embryofetal development- including the occurrence of malformations could be noted even at the high dose which showed maternal toxicity in Embryotoxicity(including teratogenicity) study with MITC in the Rabbit. The results of a lysimeter study run outdoors for two years under agricultural practices confirm that the breakdown of Dazomet in soil is rapid and leads to complete mineralization. The crop plants grown on treated soil do not contain residues of toxicological concern. The impact of Basamid granular on populations of soil dwelling organisms like earthworms, spiders, beetles and springtails was studied in field trials. Not surprisingly the numbers of animals were strongly reduced initially by the treatment, but these effects were reversible and populations recovered relatively fast and no long-lasting negative effects were observed. The group critically analyzed the information

submitted by the industry (copy of the presentation made by the industry at Annexure-III-B).

In view of the above and considering the fact that the use of product in terrace and hill agriculture shall pose problem, the group recommended as follows:

4.4 RECOMMENDATIONS:

Use of Dazomet be continued on all registered crops except tea.

5) Diflubenzuron

Diflubenzuron is a insecticide and is unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004.

5.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is severely restricted in Belize. Reasons not available. Use in cotton only.

5.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

5.2 (a) PESTICIDE CONSUMPTION IN INDIA

Data not available

5.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Diflubenzuron 25% WP - Cotton, Groundnut & public health uses.

5.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Diflubenzuron is unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004. The product is severely restricted in Belize. Use allowed in cotton only. Consumption data not available. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at Annexure- III-C). The industry in response to UN document have said that Chemtura has not registered Diflubenzuron in Belize, due to lack of a commercially significant market. Belize does not have a formal registration system. It is their understanding that individual plantations will obtain local permits to import products for specific use. Chemtura has no knowledge of any such permitted uses, nor has it submitted any data nor applied for registration in Belize. The above entry is incorrect. Considering the facts the group recommended the following:

5.4 RECOMMENDATIONS:

Use of Diflubenzuron be continued.

b) Fenpropathrin

Fenpropathrin is a pyrethroid insecticide and is moderately hazardous (Class II) as per WHO recommended Classification of Pesticides by Hazard 2004.

6.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is restricted in Korea. Due to High-toxicity to fish, shellfish, honey bee and silkworm. Uses are prohibited in neighbouring fish farms, water ways and mulberry farms during the blooming periods.

It is restricted in Malaysia because the product poses hazards under local conditions of use and alternative are available. Not allowed for manufacture, sale or import. (Except for research or educational purposes, in which case an import permit required and are subject to use with certain restrictions.

6.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

6.2 (a) PESTICIDE CONSUMPTION IN INDIA

0.0 MT Technical grade (2003- 04)
(Source States / UT's)

40 MT (2005-06) (Source: M/s Sumitomo Chemical India Pvt.Ltd.)

6.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Fenpropathrin 10%EC & 30% EC - Cotton, Chilli, Brinjal, Okra & Tea

6.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Fenpropathrin is moderately hazardous (Class II) insecticide as per WHO recommended Classification of Pesticides by Hazard 2004. Restrictions have been imposed in Korea due to high toxicity to fish, shellfish, honey bee and silkworm. Restricted in Malaysia because the product poses hazards under local conditions of use and alternative are available. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at Annexure- III-D). The industry have submitted the copies of registration Certificates obtained from Korea and Malaysia. They have said that normal restriction/precautionary statements associated with synthetic pyrethroid insecticide are in place and there is no specific restriction attributable to the molecule as special case. Considering the facts the group recommended the following:

6.4 RECOMMENDATIONS:

1. Use of Fenpropathrin be continued.
2. The label and leaflets should bear the safety precaution that it should not be used in the areas where pisciculture /aquaculture is practiced.

7) Iprodione

Iprodione is a fungicide and is unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004.

7.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is banned in Denmark because it has been assessed to be carcinogenic in category 3 and harmful to the reproduction (rep.cat.3) and the products are, therefore, seriously damaging to health. Further, assessed to be toxic and harmful to reproduction of wild birds and mammals and are therefore seriously damaging to the environment. Withdrawn from market from 31st Dec., 1997 and prohibited from 1st Aug., 1998

7.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

7.2 (a) PESTICIDE CONSUMPTION IN INDIA

Total consumption of technical in 2005 was about 14 M.T
(Source: M/s Bayer Crop Science Ltd.)

7.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Iprodione 50% WP - Rape seed/ mustard, Rice & Tomato

7.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Iprodione is technical grade active ingredient unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004. It is banned in Denmark because the product is assessed to be carcinogenic in category 3 and harmful to the reproduction (rep.cat.3) and the products are, therefore, seriously damaging to health. Further, assessed to be toxic and harmful to reproduction of wild birds and mammals and are therefore seriously damaging to the environment. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at **Annexure- III-E**). The industry has informed that ban in Denmark is a isolated case. The reason for the withdrawal was the operator exposure calculation using a safety factor of 300 instead of 100. The WHO has classified Iprodione as unlikely to present acute hazard in normal use. The product is registered in more than 50 countries. Therefore, Iprodione should be continued for use in India. Considering the facts the group recommended the following:

7.4 RECOMMENDATION:

Use of Iprodione be continued

8) Kasugamycin

Kasugamycin is a fungicide and is unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004.

8.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is Severely restricted in Belize. Reason not available. Use allowed for control of rice blast only.

8.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

8.2 (a) PESTICIDE CONSUMPTION IN INDIA

The consumption during 2003-04 ; 2004-05; 2005-06 was 120 , 130 & 145 KL respectively.

(Source: M/s Dhanuka Pesticides Ltd.)

8.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Kasugamycin 3% S.L - Rice

8.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Kasugamycin is technical grade active ingredient unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004. The product is severely restricted in Belize. Use allowed for control of Rice blast only. The group critically analyzed the information submitted by the industry(copy of the presentation made by the industry at **Annexure- III-F**) . The industry have informed that Kasugamycin is registered in Brazil, Japan, Korea, Taiwan, China, Indonesia, Bangladesh, Sri lanka, Mexico, Central America, Jamaica, Dominica, Colombia, Venezuela & Ecuador. Further, the group noted that in India its use is permitted on Rice only which is the permitted crop in Belize also. Considering the facts the group recommended the following:

8.4 RECOMMENDATION:

Use of Kasugamycin be continued

9) Linuron

Linuron is a herbicide and is unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004.

9.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is banned in U.S.S.R and is prohibited for use as pesticide because of confirmed carcinogenic in humans. Restricted in Sweden because it is carcinogenic.

9.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

9.2 (a) PESTICIDE CONSUMPTION IN INDIA

2.5 – 6 M.T

(Source: M/s Makhteshim- Agan Ltd.)

9.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Linuron 50% WP- Potato & pea

9.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that the product is banned in USSR being carcinogenic. The product is restricted in Sweden being carcinogenic. The industry submitted that carcinogenicity studies in Rats benign leydig cell adenomas in the testes of males was observed. These tumors were age related- developed in aged animals at low doses and in the control. They further submitted that the data suggests that mutagenic compounds that induce leydig cell tumors in rats, most likely have low relevance to humans under most exposure conditions, because humans are quantitatively less sensitive than rats. In carcinogenicity study in Mice, the liver tumors observed occur spontaneously in some strains of mice and were found in the control group too. The EU review between 1995- 2003 classified the product in category III, R40- Limited evidence of a carcinogenic effect. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at Annexure- III-G) . Considering the facts the group recommended the following:

9.4 RECOMMENDATIONS:

At present label claim on potato & peas may be continued subject to review after five years or whenever label expansion is being sought.

10) Mepiquat Chloride

Mepiquat Chloride is a plant growth regulator and is slightly hazardous (Class II technical grade active ingredient as per WHO recommended Classification of Pesticide by Hazard 2004).

10.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is severely restricted in Belize. Reason not available. For use as a defoliator for only cotton. It is banned in Norway because of low degradability in water. No remaining uses are allowed.

10.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA**10.2 (a) PESTICIDE CONSUMPTION IN INDIA**

The consumption of active ingredient during 2004-05 & 2005-06 was 2.4, 1.0 MT, respectively.

(Source: M/s Gharda Chemical Ltd. Mumbai)

10.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Mepiquat Chloride 50% TK & 5% AS - Potato

10.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Mepiquat Chloride is slightly hazardous (Class III) technical grade active ingredient as per WHO recommended Classification of Pesticides by Hazard 2004. The product is severely restricted in Belize. Use allowed as a defoliator for only in cotton. The product is banned in Norway because of low degradability in water. It is quaternary Ammonium compound and dissociates into cation and anion in soil. Due to cation exchange in soil it adsorbs and is not likely to contaminate water. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at Annexure- III-II) . The industry have stated that Mepiquat Chloride is not applied directly to water or to areas where surface water is present. It has a limited potential for movement to ground water. Potential metabolites like n-methylpiperidine and piperidine are not discernible. They appear to be transitory and rapidly converted to carbon dioxide. When Mepiquat Chloride is administered orally to rats, it is rapidly absorbed and finally excreted in urine. It did not accumulate in tissues. The metabolites are not detected and there is no bio-transformation of the compound. It is also extensively used in cotton and cereals in countries like U.S.A, Australia, Spain, Greece etc. Therefore, there is no concern for use of this product. Considering the facts the group recommended the following:

10.4 RECOMMENDATIONS:

Use of Mepiquat Chloride be continued

11) Propergite

Propergite is a insecticide and is slightly hazardous (Class III) technical grade active ingredient as per WHO recommended Classification of Pesticides by Hazard 2004.

11.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is restricted in Pakistan. Reason not available. No remaining uses are allowed.

11.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

11.2 (a) PESTICIDE CONSUMPTION IN INDIA

- Data not available (Source: States/UTs)

- As per information received from State Govt/UT in response to groups requests, Andhra Pradesh informed that the consumption during 2004-05 was 21 MT tech. grade

11.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Propergite 57 EC - Tea & Chillies

11.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Propergite is slightly hazardous (Class III) technical grade active ingredient as per WHO recommended Classification of Pesticides by Hazard 2004. It is restricted in Pakistan. Reason not available. No remaining uses are allowed. The industry has informed that the entry in UN document is incorrect. Propergite is registered for use in Pakistan. They further informed that the product is registered in over 50 countries around the world including USA and EU. Birsa Agricultural University Ranchi has informed that it is recommended against a variety of mite pests infesting various crops and is an emerging acaricide in different corners of our country. It is recommended as a package of practices by Y.S. Parmar University of Horticulture and Forestry, Solan. Further, the group did not come across any other concern due to use of this pesticide. Considering the facts the group recommended the following:

11.4 RECOMMENDATIONS:

Use of Propergite be continued

12) Propineb

Propineb is a fungicide and is unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004.

12.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is voluntarily withdrawn from the market in Sweden. Reason not available.

12.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

12.2 (a) PESTICIDE CONSUMPTION IN INDIA

About 581 M.T of technical was consumed in India in the year 2005. (Source: M/s Bayer Crop Science Ltd.)

12.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Propineb 70% WP - Apple, Pomegranate, Potato, Chilli & Grapes

12.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Propineb is technical grade active ingredient unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004. Propineb has a goitrogenic effect. Following oral administration, high tissue concentration in, and enlargement of the thyroid and pituitary gland occurs. Significant thyroid enlargement occurred in the males at dietary levels of 100 ppm and above. The product is banned in Sweden. Reason not available. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at Annexure- III-i). The industry informed that Swedish Bayer subsidiary in 1992 decided to voluntarily withdraw Propineb containing formulations due to economic reasons. Propineb containing products are registered in numerous countries for use in a wide range of crops, including Australia, France, Japan and U.K. Regarding effect on thyroid, the industry informed that the thyroid effects occurred only in the rat and thyroid enlargement is reversible. Mechanism of thyroid suppression is clearly understood. Rat thyroid neoplasia not relevant to human. ADI(0.007 mg/kg b.w./day) is safe since based on the NOAEL of the unrealistically sensitive rat. There is large margin of safety for human between ADI and thyroid weight increase in rat. Considering the facts the group recommended the following:

12.4 RECOMMENDATIONS:

Use of Propineb be continued

13) Thiodicarb

Thiodicarb is an insecticide and is moderately hazardous (Class II) as per WHO recommended Classification of Pesticides by Hazard 2004.

13.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is restricted in Belize because of high toxicity. Severely restricted for use only in cotton.

13.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA**13.2 (a) PESTICIDE CONSUMPTION IN INDIA**

About 253 M.T of technical was consumed in India in the year 2005.
(Source: M/s Bayer Crop Science Ltd.)

13.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Thiodicarb 75% WP - Cabbage, Cotton & Brinjal

13.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that thiodicarb is moderately hazardous (Class II) insecticide as per WHO recommended Classification of Pesticides by Hazard 2004. It is severely restricted for use only in cotton in Belize due to high toxicity. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at Annexure-III-J). The industry have informed that the restriction on cotton in Belize is an isolated case. Thiodicarb containing products are registered and sold in almost 25 countries throughout the world on almost 50 crops. Therefore, this should be continued to be used in India. Further, the group did not come across any other concern due to use of this pesticides. Considering the facts the group recommended the following:

13.4 RECOMMENDATIONS:

Use of Thiodicarb be continued.

14) Trichlorofon

Trichlorofon is an insecticide and is moderately hazardous (Class II) as per WHO recommended Classification of Pesticides by Hazard 2004.

14.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is restricted in Indonesia. Reason not available. Still allowed for use until 1996 only for recommended target crop as well as target pest. Use under the provision of supervision. It is banned in Kuwait because of health and environmental reasons. No remaining uses are allowed.

14.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

14.2 (a) PESTICIDE CONSUMPTION IN INDIA

Data not available

14.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Trichlorofon 5 G, 5 DP & 50 EC - Maize, Sorghum Castor, Groundnut, Wheat, Sesamum, Brinjal, Cabbage, Cauliflower, Coffee, Tobacco, Cauliflower, Cucurbits, & Tomato

14.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that trichlorofon is moderately hazardous (Class II) insecticide as per WHO recommended Classification of Pesticides by Hazard 2004. It is restricted in Indonesia. Reason not available. Still allowed for use until 1996 only for recommended target crop as well as target pest. Use under the provision of supervision. It is banned in Kuwait because of health and environmental reasons. No remaining uses are allowed. The industry submitted that in Kuwait the economic crops are oilpalms and dates and Trichlorofon is not approved for use in oilpalms and dates in India. Also, Indian agro-climatic conditions cannot be compared with that of Kuwait. Therefore, the ban in Kuwait is not truly relevant in Indian context. It is registered and used in more than 40 countries including the U.S.A and Japan. No adverse effect reported either on efficacy or toxicity, despite its use for over 3 decades. The group did not come across any other concern due to use of this pesticide. The group critically analyzed the information submitted by the industry (copy of the presentation made by the industry at Annexure-III-K). Considering the facts the group recommended the following:

14.4 RECOMMENDATION:

Use of Trichlorofon be continued with following precautions:

- i) It should not be used near areas where aquaculture is practiced.
- ii) Its use as seed dresser and late stage spray on crops should be avoided.

15) Simazine:

Simazine is a herbicide and is unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004.

15.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is banned in Norway because of high mobility, persistence in soil and water & extremely toxic to algae. No remaining uses are allowed.

15.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

15.2 (a) PESTICIDE CONSUMPTION IN INDIA

45 MT Technical grade (2003- 04)
(Source States / UT's)

15.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Simazine 50% WP - Sugarcane, Maize & Tea

15.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Simazine is technical grade active ingredient unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004. It is banned in Norway because of high mobility, persistence in soil and water & extremely toxic to algae. No remaining uses are allowed. Considering the facts the group recommended the following:

15.4 RECOMMENDATIONS:

The product has been withdrawn vide Notification No. S.O 915(E) dated 15th June, 2006. The withdrawal made by the Government pursuant to this order shall become inoperative as soon as the required data for the insecticide (s) as per the guidelines is generated and submitted by the Pesticide Industry to be Government and accepted by the Registration Committee. Therefore, the Expert Group decided that the Registration Committee may review this pesticide from all angles as and when data are submitted by the pesticides Industry.

16) Dalapon:

Dalapon is a herbicide and is unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004

16.1 THE BAN/RESTRICTION STATUS INTERNATIONALLY

It is banned in Austria because of High mobility in soil and therefore high risk of contamination of water. High aquatic toxicity. All uses banned. Dalapon has been detected in drinking water. It is banned in Norway because of mobility and high persistence in soil. No remaining uses are allowed.

16.2 THE PRESENT STATUS OF THE PESTICIDE USE IN INDIA

16.2 (a) PESTICIDE CONSUMPTION IN INDIA

17 MT Technical grade (2003- 04)
(Source States / UT's)

16.2 (b) FORMULATIONS REGISTERED AND THEIR LABEL CLAIMS.

Dalapon 85%WP Na Salt - Rubber, Tea, Jute, Forestry & Mesta

16.3 MAJOR CONCERNS OF THE COMMITTEE REGARDING CHEMISTRY, TOXICITY, RESIDUE PERSISTENCE AND RESISTENCE:

The group noted that Dalapon is technical grade active ingredient unlikely to present acute hazard in normal use as per WHO recommended Classification of Pesticides by Hazard 2004. It is banned in Austria because of High mobility in soil and therefore high risk of contamination of water. High aquatic toxicity. All uses banned. Dalapon has been detected in drinking water. It is banned in Norway because of mobility and high persistence in soil. No remaining uses are allowed. Considering the facts the group recommended the following:

16.4 RECOMMENDATIONS:

The product has been withdrawn vide Notification No. S.O 915(E) dated 15th June, 2006. The withdrawal made by the Government pursuant to this order shall become inoperative as soon as the required data for the insecticide (s) as per the guidelines is generated and submitted by the Pesticide Industry to be Government and accepted by the Registration Committee. Therefore, the Expert Group decided that the Registration Committee may review this pesticide from all angles as and when data are submitted by the pesticides Industry.

Annexure

Review of various pesticides which are banned/ restricted in other countries but are being used in India

S.No.	Name of Pesticides	S.No.	Name of Pesticides
1	Monocrotophos	20	Dinocap
2	Mancozeb	21	Ethofenprox (Etofenprox)
3	Quinalphos	22	Metoxuron
4	Butachlor	23	Trifluralin
5	Diclorvos (DDVP)	24	Chlorofenvinphos
6	Acephate	25	Fenprophrin
7	Fenitrothion	26	Iprodione
8	Carbendazim	27	Benfuracarb
9	Atrazine	28	Bifenthrin
10	Pendimethalin	29	Dazomet
11	Deltamethrin (Decamethrin)	30	Diflubenzuron
12	Fenthion	31	Kasugamycin
13	Simazine	32	Linuron
14	Metalddehyde	33	Mepiquate Chloride
15	Diazinon	34	Propergite
16	Carbosulfan	35	Propineb
17	Chlorothalonil	36	Thiodicarb
18	Dalapon	37	Trichlorofon
19	Thiophanate-Methyl		

The terms of reference of the Expert Group ;

- I. To review toxicity, persistences, safety in use and substitute available of 37 pesticides (List at APPENDIX I) and make recommendations for their continued use or restricted use or phasing out in the country.
- II. The review may be done in phased manner. In the first phase those pesticides whose consumption is more than 100 MT per annum, may be reviewed. In the next phase pesticide whose consumption is between 99- 11 M.T. and in the third phase whose consumption is less than 10 M.T or data not available may be reviewed. [As per the pesticide consumption information 2003-2004, the pesticide to be reviewed in different phases are indicated in the enclosed list at APPENDIX I.]
- III. The Expert group can co-opt any Member for conducting the business.
- IV. The group may evolve its own procedure and methodology of functioning and call for any relevant data from any department of the Central / State Government / Private Organization/persons etc.
- V. The TADA of the Members of the Expert Group will be met by the Organizations from where their pay is being drawn.
- VI. The expert group may give the report within six months for the pesticide to be reviewed in the first phase, in the next 6 months for pesticides to be reviewed in the second phase and further 6 months in the third phase.

S.No.	Name of the Pesticide	Consumption (M.T) Tech. Grade year 2003-04
1	Monocrotophos	
2	Mancozeb	
3	Quinalphos	3115 *
4	Butachlor	2515 *
5	Diclorvos (DDVP)	1650 *
6	Acephate	1520 *
7	Fenitrothion	818 *
8	Carbendazim	440 *
9	Atrazine	412 *
10	Pendimethalin	400 *
11	Deltamethrin (Decamethrin)	315 *
12	Fenthion	140 *
13	Simazine	83 **
14	Metalddehyde	62 **
15	Diazinon	45 **
16	Carbosulfan	42 **
17	Chlorothalonil	40 **
18	Dalapon	35 **
19	Thiophanate-Methyl	35 **
20	Dinocap	17 **
21	Ethofenprox (Etofenprox)	15 **
22	Metoxuron	13 **
23	Trifluralin	11 **
24	Chlorofenviaphos	10 **
25	Fenpropathrin	8 ***
26	Iprodione	6 ***
27	Benfuracarb	6 ***
28	Bifenthrin	
29	Dazomet	Data Not Available ***
30	Diffubenzuron	Data Not Available ***
31	Kasugamycin	Data Not Available ***
32	Linuron	Data Not Available ***
33	Mepiquate Chloride	Data Not Available ***
34	Propergite	Data Not Available ***
35	Propineb	Data Not Available ***
36	Thiodicarb	Data Not Available ***
37	Trichlorofon	Data Not Available ***

1999-2000
1999-2000

* Proposed to be reviewed in the first phase
 ** Proposed to be reviewed in the second phase
 *** Proposed to be reviewed in the third phase

-3-

CONSUMPTION OF INDIGENOUS PESTICIDES IN AGRICULTURE FOR THE LAST FIVE YEARS (1999-2000 TO 2003-2004)

S. No.	Pesticides	Group	M.T. (Tech. Grade)				
			1999-2000	2000-01	2001-02	2002-03	2003-04
1.	Acephate	i					
2.	Cypermethrin	i	697	674			
3.	Dichlorvos	i	957	1035	750	782	440
4.	Dimethoate	i	971	102	1300	1315	32
5.	Endosulphan	i	1505	1277	1070	1250	815
6.	Emion	i	3170	2820	1500	2009	625
7.	Fenitrothion	i	239	385	3985	2000	2900
8.	Fenthion	i	239	385	415	410	315
9.	Fenvalerate	i	34	38	415	410	412
10.	Lindane	i	695	1085	60	79	62
11.	Metal Dehyde	i	607	683	2100	1192	975
12.	Malathion	i	42	43	700	615	=
13.	Methyl Parathion	i	2635	2486	32	40	07
14.	Monocrotophos	i	2705	2639	2600	2384	3015
15.	Neem based insecticides	i	3496	2680	3008	3028	3200
16.	Oxydemeton methyl	i	739	551	2815	3205	3115
17.	Paradichloro-benzene	i	432	384	736	632	824
18.	Phorate	i	0	0	512	382	215
19.	Phosphamidon	i	2006	2133	0	0	1
20.	Phosphanon	i	224	185	2215	2316	3010
21.	Quintopos	i	1746	1023	218	275	145
22.	Sevidol	i	10	10	1100	1020	1480
23.	Teaepos	i	1906	13	13	10	11
24.	Triazophos	i	0	1858	2181	10	11
25.	Aureofungin	i	0	0	0	2318	1650
26.	Caprafol/Difolaton	f	107	0	0	0	0
27.	Captan	f	10	118	0	0	1
28.	Carbendazin	f	144	6	114	108	115
29.	Copper Oxychloride	f	218	227	3	5	12
30.	Copper Sulphate	f	514	156	419	344	15
31.	Cuprous Oxide	f	1081	464	170	256	200
32.	Ethyl Mercury Chloride	f	592	955	625	859	400
33.	Ferban	f	2	692	1122	1213	1080
34.	Lime Sulphur	f	0	0	1042	1128	514
35.	Mancozeb	f	15	0	5	2	5
36.	MEMC	f	16	10	0	0	0
37.	Organo Mercurials	f	2200	22	25	9	12
38.	Nickel Chloride	f	85	1939	32	45	20
39.	Paris Green	f	0	87	2577	2800	2615
40.	PMA	f	21	0	71	81	22
41.	Streptocycline	f	0	40	0	0	0
42.	Sulphur	f	0	0	55	60	0
43.		f	26	0	0	0	0
		1989	31	0	0	0	0
			2085	39	47	20	
			2332		3185	3010	

44.	Thiram	f	405	403	419	402	302
45.	Zineb	f	215	213	318	313	205
46.	Ziram	f	194	192	277	285	100
47.	Alachlor	h	153	123	142	150	95
48.	Auilophos	h	380	402	535	716	200
49.	Butachlor	h	2332	2161	2019	2430	1520
50.	Dalapon	h	11	51	72	85	17
51.	2,4-D	h	680	678	612	680	612
52.	Diuron	h	11	5	12	11	10
53.	Fluchloralin	h	105	149	155	213	115
54.	Glyphosate	h	178	154	180	178	162
55.	Isoproturon	h	2649	2742	2512	2618	2208
56.	Paraquat Dichloride	h	113	165	110	156	70
57.	Propanil	h	0	0	0	0	30
58.	FCA	h	0	0	0	0	15
59.	Aluminium Phosphide	r	250	265	234	250	142
60.	Barium Carbonate	r	0	0	0	0	0
61.	EDCT Mixture	r	0	0	0	0	0
62.	EDB	r	22	18	18	23	0
63.	Methyl bromide	r	5	2	4	7	7
64.	Warfarin	r	4	4	6	10	1
65.	MB-FDB	r	0	0	0	0	0
66.	Zinc Phosphide	r	207	223	220	389	215
67.	Alpha naphthyl acetic acid	pg	41	27	18	19	25
68.	Chloroquat chloride	pg	4	5	12	4	10
69.	Others		734	604	0	0	0
	TOTAL:	Indefinite	41101	38796	43800	45130	37352

Source: States/UTs

- i - Insecticide
- f - Fungicide
- h - Weedicide
- r - Rodenticide
- fm - Fumigants
- pg - Plant growth regulator
- mp - Misc. pesticides

CONSUMPTION OF REPORTED PESTICIDES DURING THE LAST FIVE YEARS
(1999-2000 TO 2003-04)

Sl. No.	Pesticides	Group	M.T. (Tonn. Grade)				
			1999-2000	2000-01	2001-02	2002-03	2003-04
1.	Aldicarb	i	0	0	0	0	0
2.	Allethrin	i	20	11	5	8	9
3.	Alpha cypermethrin	i	30	27	7	16	12
4.	Bacillus thuringiensis	i	135	132	166	143	157
5.	Carbaryl	i	611	543	155	219	273
6.	Carbofuran	i	589	786	419	308	500
7.	Carbosulfan	i	133	29	17	20	35
8.	Cartap hydrochloride	i	56	63	34	26	29
9.	Cyfluthrin	i	0	0	0	0	5
10.	Chlorfenvinphos	i	4	18	0	0	8
11.	Chlorpyrifos	i	912	929	71	6	1161
12.	Cyphenothrin	i	0	0	718	825	8
13.	Deltamethrin	i	0	0	0	0	8
14.	Diazinon	i	166	136	0	0	8
15.	Dicofol	i	62	63	106	96	33
16.	Ethofenprox	i	357	110	31	35	40
17.	Fenmethion	i	11	10	73	56	52
18.	Fenabucarb (DZMC)	i	57	35	2	5	11
19.	Fenpropathrin	i	11	27	10	3	8
20.	Fipronil	i	1	0	8	9	6
21.	Fluralinate	i	11	0	0	0	0
22.	Lamdocyhalothrin	i	9	40	10	7	13
23.	Mathionyl	i	16	10	6	5	7
24.	Permethrin	i	55	83	35	41	28
25.	Phenthoate	i	12	66	41	38	10
26.	Propoxur	i	84	4	2	4	3
27.	Prostemphos	i	1	52	38	57	35
28.	Profenfos	i	0	2	1	1	0
29.	Thiometon	i	0	0	0	0	0
30.	Beaucmyl	f	35	82	0	0	45
31.	Bitertanol	f	3	2	60	39	1
32.	Carboxin	f	21	31	1	1	13
33.	Chlorthalonil	f	2	1	10	12	3
34.	Dodin	f	23	1	1	2	10
35.	Dithianon	f	35	29	14	12	15
36.	Dinocap	f	33	27	16	12	15
37.	Ediphenphos	f	0	35	2	27	6
38.	Fosstyl-Al	f	14	12	6	1	0
39.	Hexaconazole	f	57	17	12	8	13
40.	Iprodione	f	35	37	22	19	20
41.	Isoprothiolane	f	26	53	14	25	18
42.	Kitazin	f	1	37	9	17	14
43.	Kasugamycin	f	4	0	0	7	0
		f	78	16	11	0	7
		f	0	69	63	6	70
		f	17	3	63	63	10

44.	Metolaxyl	f	28	32	25	21	6
45.	Penconazole	f	i	1	1	0	0
46.	Propiconazole	f	26	16	7	5	9
47.	Tridemorph	f	269	280	115	125	120
48.	Thiophanate methyl	f	31	40	20	19	15
49.	Triadimenfon	f	9	18	13	11	1
50.	Tricyclazole	f	13	16	6	15	11
51.	Validamycin	f	2	1	2	1	3
52.	Atrazine	h	346	330	390	325	315
53.	Benthiocarb	h	98	112	147	140	135
54.	Methabenzthiazuron	h	9	0	0	0	8
55.	Metoxuron	h	25	23	42	38	10
56.	Metribuzin	h	2	0	0	0	0
57.	Metolachlor	h	0	0	0	0	2
58.	Oxadiazon	h	2	4	8	8	3
59.	Oxidimetryl	h	0	2	3	5	2
60.	Oxyfluorfen	h	6	3	5	2	6
61.	Pendimethalin	h	161	126	130	149	140
62.	Partilachlor	h	31	12	15	12	13
63.	Simazine	h	84	42	55	64	45
64.	Triflats	h	0	0	0	0	1
65.	Trifluralin	h	8	13	7	11	10
66.	Bromedione	r	74	47	79	83	50
67.	Ethepon	pg	7	5	3	1	0
68.	Gibberellic Acid	pg	10	13	12	10	15
69.	Melic hydrazide	mp	6	0	0	0	0
70.	DD Mixture	n	0	0	0	0	0
71.	Others	n	0	0	0	0	0
	TOTAL:		101	9	0	0	0
		Unreported	30994	47888	3220	3220	3668
		Undeclared	41101	38796	43800	45130	37352
	Grand Total:		46195	43584	47020	48350	41020

Source: States/UTs

Note: i - Insecticide
 f - Fungicide
 h - Herbicide
 r - Rodenticide
 fu - Fumigants
 pg - Plant growth regulator
 mp - Misc. pesticides



BENFURACARB(ONCOL)-

**A CARBAMATE
INSECTICIDE**

Dr. A. Kuppusamy

**M/s. Coromandel Fertilisers
Limited, 1-2-10 Sardar Patel
Road, Secunderabad,**

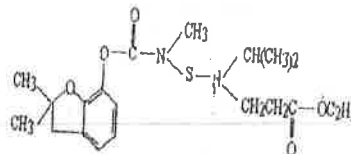


*** Issue : Restricted in Korea due to High
Acute Toxicity**

*** BUT , THE PRODUCT IS NOT
RESTRICTED IN KOREA**

Benfurcarb Chemistry

- * Common Name : Benfurcarb
- * Chemical Name : 2,3-dihydro-2,2-dimethyl-7-benzofuranyl 2-methyl-4-(1-methyl ethyl)-7-oxo-8-oxa-3-thia-2,4-diazadecanoate
- * CAS No. : 82560-54-1
- * Mol. Formula : $C_{20}H_{30}N_2O_5S$
- * Structural formula:



BENFURACARB (ONCOL) History

- * Benfurcarb is reported as Insecticide in 1983
- * Technically manufactured by M/s Otsuka Chemicals, Japan, Otsuka Chemical is basically a Research oriented pharmaceutical/Agrochemical company in Japan
- * Oncol is being successfully used in several countries like Japan, France, Argentina, Italy, Brazil, USA, UK etc. (in total 60 countries)
- * Effective against wide range of insect pests on 30 major crops

REGISTRATION IN INDIA

- # Registered u/s. 9(3) of I. A, 1968 .
- # Benfurcarb technical for Import From Japan.

- Benfurcarb 40% EC for FIM
- Benfurcarb 3.0% G for FIM

We have Submitted all the Data as per the guidelines for 9(3) as per the Insecticides Act, 1968..

- After Complete scrutiny of data on Chemistry, Toxicology, Bioefficacy and packaging, CIBRC has Approved the above Registrations in 240th RC meeting.

All the Chemistry Toxicology , Bioefficacy Data are Available with CIBRC

REGISTRATION IN INDIA

- # Cleared in 240th RC meeting on 04.11.2003
- # Certificates received after 8 months on 30.07.2004 (Delayed due to MRL issue)
- # First Import of technical in Sept,04
- # First Introduction of Benfurcarb 40% EC in Kharif , 2005
- # Benfurcarb 3.0% G will be Introduced by April,2007

BENFURACARB - MODE OF ACTIONS



Carbamate Insecticides

- ☐ Broad spectrum action
- ☐ Systemic,
- ☐ Contact and
- ☐ Stomach action
- ☐ Cholinesterase inhibitor
- ☐ Nematicidal action

BENFURACARB - EFFECTIVENESS



Oneol provides control of

- ☐ Lepidopteran pests (Caterpillars, Fruit borers, bollworm, pod borers, stem borers etc)
- ☐ Coleopteran pests (Beetles ,Weevils)
- ☐ Thysanopteran pests (Thrips)
- ☐ Hemipteran and Homopteran (Aphids and Jassids)
- ☐ Dipteran pests (Leaf miners, gall midge)

Types of Benfuracarb Formulations available- world wide



ONCOL 1G, 3G, 5G, 8.6G, 10G	Granules for broadcast, band and furrow applications and nursery box treatment.
ONCOL 10EC, 20EC, 30EC, 40EC ONCOL 20WG, 30WG	Emulsifiable concentrates and water dispersible granules for foliar and soil applications.
ONCOL 25WP, 40WP (WS)	Wettable powders or water dispersible powders for slurry seed treatment for foliar and soil applications and seed treatment.
ONCOL 20CS, 30CS, 40CS	Capsule suspensions for foliar application and seed treatment.

In India, 40% EC and 3.0% G registered

BENFURCARB - ACUTE TOXICITY



No.	DATA	LD 50 mg/kg of body weight
1	Acute Oral Rat LD50	213.7
2	Acute Oral Mice LD 50	139.22
3	Acute Dermal LD50 for rat	> 2000
4	Acute Inhalation LC 50(4 Hrs)	0.344 mg/lit air
5	Primary Skin Irritant	Non Irritant
	Primary Eye Irritant	Non-Irritant

BENFURCACARB- MUTAGENICITY



NAME OF THE TEST	DOSAGE USED	RESULTS
In vitro micronucleus assay test	1,0,5 and 50 mg/kg	Treated mice produced No significant increases in the frequency of micronuclei in the polychromatic erythrocyte stem cell NEGATIVE
In vitro bone Marrow Chromosome study in rat	0,5,15 and 50 mg/kg	No statistically significant increases in the frequency of chromosome aberrations compared to control values were seen for any of the dose levels in either the acute or sub acute portion of the study NEGATIVE
Determine The ability to induce the unscheduled DNA synthesis in HeLa Cells	0,5,15 and 50 mg/kg	Did not induce unscheduled DNA synthesis in HeLa cells in the presence or absence of a rat liver metabolizing system under the conditions used. NEGATIVE

Summary of Short term Toxicity



- * Short term Toxicity -NOAEL (Acute)
 - ☐ Rat - 200 ppm i.e. 12 mg/kg bw/day.
 - ☐ Mouse -50 mg/kg bw/day
 - ☐ NOAEL -Dermal Rat : >125 mg/kg bw/day

Summary of short term-toxicity of benfuracarb

Type of test Test species	Test substance Purity	Results			References
		NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Symptoms	
35 day oral rat, diet 300, 600, 1200 and 2400 ppm	Lot n° 1J83, 93.03%	<300ppm =2667 mg/kg bw/d	300 ppm= 24.67 mg/kg bw/d	Dose-related clinical signs (hunched posture, rough hair coat) Decreased body weight Dose-related inhibition of plasma cholinesterase	Cox and Ralph, 1982
4- week oral rat, gavage 2, 20, 40-160mg/kg bw/d	Batch n° 5173, 91.36%	2 mg/kg bw/d	20 mg/kg bw/d	Reduced bw, food and water consumption, clinical signs of neurotoxicity, reduced prostate and atrophic seminal vesicle, increased incidence of moderate to severe depression of brain cholinesterase transformation	Korn, 1987a
49 day oral mice, diet, 111, 190, 223, 299, 400 mg/kg bw/d	Batch n° 1J83, 93.03%	<111 mg/kg bw/d	111 mg/kg bw/d	Dose-related increase of clinical signs, altered hematological parameters, decreased plasma cholinesterase	Beiko and Nogai, 1982
13 week feeding rat study, 260, 400, 800 ppm	lot n° 1K 85, 94.6%	<200 ppm =13.6 mg/kg bw/d	200 ppm =13.6 mg/kg bw/d	Dose-related increase of clinical signs, altered hematological parameters, decreased plasma cholinesterase	Cox and Burns, 1982
13 week feeding mice study, 160, 300, 1000 ppm	Batch n° 1J83, 93.03%	300 ppm =4762 mg/kg bw/d	1000 ppm =16222 mg/kg bw/d	Tranquility, piloerection, ptosis	Nishinura et al, 1982
13 week feeding rat study, 30, 300, 900-1000- 1200	Batch n° S173; purity?	30 ppm (±3 mg/kg bw/d, estimated	300 ppm	Clinical signs, body weight decrease	Korn, 1987b

Summary of short term-toxicity of benfuracarb- contd.

52 week feeding rat study 200-800-800 ppm	Batch n° 1K85, 93.6%	=300ppm (11.89 mg/kg bw/d)	400 ppm	Altered body weight, increased BUN, and increased incidence of ovary cysts	Kox, 1983
13 week feeding dog study, 25, 100, 400- 1000 ppm	Batch n° 5173, 91.36%	25 ppm (=0.625 mg/kg bw/d)	100 ppm	Involution of thymus, observed at 100 ppm onwards	Korn, 1987c
6 month dog study, gelatin capsules, 2.5; 5; 10 mg/kg bw/d	Lot n° 2A79; 94.8%	2.5 mg/kg bw/d	5 mg/kg bw/d	Excretion of viscous feces, twitch and dilation of hind limbs after administration, every day, throughout the administration period.	Kato et al., 1982
17-24 month dog study, gelatin capsules, 2.5; 5; 10 mg/kg bw/d	Lot n° 2A79, 94.8%	=25 mg/kg bw/d	5 mg/kg bw/d	Clinical signs of neurotoxicity associated with plasma AChE inhibition	Ishikura et al, 1984
29 day, dermal rat study, 5, 25, 125 mg/kg bw/d	Batch n° GD96, 93.4%	Systemic toxicity = 5 mg/kg bw/d. Local effects > 125 mg/kg bw/d	25 mg/kg bw/d	Plasma cholinesterase inhibition correlating with clinical signs of toxicity	Van Otterdijk, 2001

Summary of long-term toxicity and carcinogenicity of benfuracarb



Type of test Test species	Test substance Purity	Results			References
		NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Symptoms	
Rat, 104 week study, 100, 200, 400 ppm	Batch n° 1K85, 92.6%	= 100 ppm (5.5 mg/kg bw/d)	200 ppm	clinical signs brain and RBCs cholinestera se inhibition	Cox, 1984
Rat, 104 week study, 25 ppm	Batch n° 1K85, 92.6%	> 25 ppm(1.5 mg/kg bw/d)	-	-	Cox, 1986
Mice, 18 month study, 100, 300, 1000 ppm	Batch n° 1L88, purity 93.6%	100 ppm (15.4mg/kg g bw/d)	300 ppm (45.1 mg/kg bw/d)	Body weight alterations	Benke, 1984

Summary of reproductive toxicity and teratogenicity of benfuracarb

Type of test Test species	Test substance Purity	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Symptoms	References
2-generation, 25; 100 and 400 ppm	Batch n° 1L88, purity 93.6%	Reprod tox: 25 ppm (1.2mg/kg bw/d)	100 ppm = 4.8 mg/kg bw/d	F1: ↓ pregnancy rates and ↓ fertility indices	Schroeder, 1984
		Chronic tox: 25 ppm (1.2 mg/kg bw/d)	100 ppm = 4.8 mg/kg bw/d	↓ parental bw	
		embryotox: 25 ppm (1.2 mg/kg bw/d)	100 ppm = 4.8 mg/kg bw/d	↓ Litter survival index, F2	
Developmental rat: 2, 10, 40 mg/kg bw/d	Batch n° 1K85, purity 92.6%	Maternal toxicity: 2 mg/kg bw/d	10 mg/kg bw/d	↓ Maternal bw	Schroeder, 1983a
		Developmental toxicity: 10 mg/kg bw/d	40 mg/kg bw/d	↑ Delayed or incomplete ossification	
		Embryotoxicity: 10 mg/kg bw/d	40 mg/kg bw/d	↓ BW (fetus)	
Developmental rabbits: 5, 10, 15 mg/kg bw/d	Batch n° 1K85, purity 92.6%	Embryotoxicity = 10 mg/kg bw/d	15 mg/kg bw/d	Reduced fetal weights	Schroeder, 1983b
		NOAEL maternal toxicity = 5mg/kg bw/d	10 mg/kg bw/d.	Ano-genital staining	
		developmental tox = 15 mg/kg bw/d.	-	-	

Summary of acute delayed neurotoxicity in hens

Type of test Test species	Test substance Purity	Endpoints	Symptoms	References
Acute delayed neurotoxicity study, hens	97%, batch n° 1K85	LD50 = 92 mg/kg bw	Benfurcarb does not induce delayed neurotoxicity	Auletto and Loder (1982)
28-day rat neurotoxicity study	94.51%; lot n° 2j03	NOAEL neurotoxicity = 25 ppm (1.81 mg/kg bw/d)	at 125 ppm (9.4 mg/kg bw/d): sloped feet, hunchback posture, inhibition of plasma, brain and erythrocyte AChE	Shutoh, (2003)

ADI, AOEL, ARFD for Benfurcarb



Summary	Value	Study	Safety factor
ADI	0.01 mg/kg bw/d	2 generation rat studies, 13 week feeding dog	100
AOEL	0.01 mg/kg bw/d	13 week, 6 month, 1 and 2 year dog studies	100
ARFD (acute reference dose)	0.02 mg/kg bw/d	28 day, rat neurotoxicity study	100

Medical Data



- * Medical examination of workers participating in the manufacturing process of benfuracarb Technical did not display any adverse signs or symptoms.
- * Medical examination of workers participating in the manufacturing process of benfuracarb 40% EC did not display any adverse signs or symptoms.

BENFURACARB- WHO CLASIFICACION



**BENFURACARB
CLASSIFIED AS CLASS
II (MODERATELY
HAZARDOUS PRODUCT)
AS PER WHO.**

WORLD HEALTH ORGANIZATION



1969-1978 MONITOR OF THE ENVIRONMENT



International Programme on Chemical Safety
115, Route des Morillons
CH-1150 Chêne-Boulogne
Switzerland
Tel: 022 765 1111
Telex: 260333
Fax: 022 765 1111

1980-1989
1990-1999
2000-2009
2010-2019
2020-2029
2030-2039
2040-2049
2050-2059
2060-2069
2070-2079
2080-2089
2090-2099

Doc. No. 1000

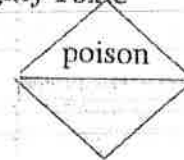
It is recommended that the label of Benfuracarb should be amended to indicate that it is a moderately hazardous product (Class II) and that it is not a carcinogen. The label should also indicate that it is a moderately hazardous product (Class II) and that it is not a carcinogen. The label should also indicate that it is a moderately hazardous product (Class II) and that it is not a carcinogen.

Yves Gaudin
Director of Public Health
International Programme on Chemical Safety

Benfurcarb - Toxicity Classification



- * Class II (moderate toxic) as per WHO
- * As Per Indian Regulatory System it is Highly Toxic
- * Acute Oral LD₅₀ (Rats) - 213 mg/kg.
- * Acute Dermal LD₅₀ (Rats) - > 2000mg/kg.
- * Triangle : Yellow



Approved Label for Benfurcarb 40% EC



Crop Name	Pest Name	Dosage A.I(kg)	Dosage Formulation (ml)	Waiting Period from last spray to harvest (Days)
Red gram	Podborer	1	2500	20

Label claim for
Benfuracarb 3.0% G



Crop Name	Pest Name	Dosage A.I (kg)	Dosage Formulation (kg)	Waiting Period from last spray to harvest (Days)
Rice	Stem Borer, Leaf folder, BPH	1	33	20

BENFURACARB REGISTRATION
MRL FIXED IN JAPAN



- # oncol\Benfuracarb 5G 20SC usage in Japan.xls
- # oncol\Table of MRLs for agricultural chemicals. tm

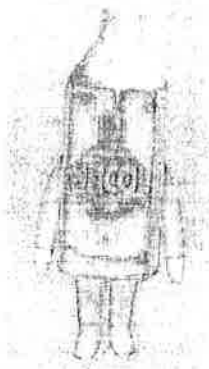
Benfurcarb 40% EC (Oncol) Sales in India



STATE	2005-06	2006-07	2007-08 (Plan)
GUJARAT	1880	10000	20000
KARNATAKA	1500	7500	15000
PUNJAB	1596	5000	10000
MADHYA PRADESH	1320	4000	7500
ORISSA	2000	5000	8000
WEST BENGAL	1000	5500	7000
ANDHRA PRADESH	2561	25000	40000
MAHARASTRA	760	4990	15000
CHHATTISGARH	0	2300	3000
TAMILNADU	1821	4000	3000
BIHAR	0	500	2000
JHARKHAND	0	700	5000
UTTAR PRADESH	0	200	2000
Grand Total	14437	74690	137500

2006-07:
(Estimated upto
March,07)

Sales Promotion Tools



Oncol Inflatable



Oncol Poster Design



BENFURACARB REGISTRATION STATUS - WORLDWIDE



Benfuracarb Registered & use in the following countries

Otsuka Chemical Co., Ltd.
 1-1-1 Otsuka, Bunkyo-ku, Tokyo, 113, Japan
 TEL: 03-433-1111 FAX: 03-433-1111

- Romania
- South Africa
- Spain
- Thailand
- Taiwan
- Turkey
- United Kingdom
- Uruguay
- Venezuela
- Vietnam
- Yugoslavia
- Zimbabwe

Country	Registration No.	Trade Name	Registration Status
Algeria	1000000	OTSUKA 1000	Registered
Argentina	1000000	OTSUKA 1000	Registered
Australia	1000000	OTSUKA 1000	Registered
Brazil	1000000	OTSUKA 1000	Registered
Canada	1000000	OTSUKA 1000	Registered
China	1000000	OTSUKA 1000	Registered
France	1000000	OTSUKA 1000	Registered
Germany	1000000	OTSUKA 1000	Registered
India	1000000	OTSUKA 1000	Registered
Italy	1000000	OTSUKA 1000	Registered
Japan	1000000	OTSUKA 1000	Registered
Korea	1000000	OTSUKA 1000	Registered
Malaysia	1000000	OTSUKA 1000	Registered
Mexico	1000000	OTSUKA 1000	Registered
Netherlands	1000000	OTSUKA 1000	Registered
Philippines	1000000	OTSUKA 1000	Registered
Portugal	1000000	OTSUKA 1000	Registered
Romania	1000000	OTSUKA 1000	Registered
South Africa	1000000	OTSUKA 1000	Registered
Spain	1000000	OTSUKA 1000	Registered
Thailand	1000000	OTSUKA 1000	Registered
Taiwan	1000000	OTSUKA 1000	Registered
Turkey	1000000	OTSUKA 1000	Registered
Uruguay	1000000	OTSUKA 1000	Registered
Venezuela	1000000	OTSUKA 1000	Registered
Vietnam	1000000	OTSUKA 1000	Registered
Yugoslavia	1000000	OTSUKA 1000	Registered
Zimbabwe	1000000	OTSUKA 1000	Registered

Otsuka Chemical Co., Ltd.
 President
 Otsuka Chemical Development Dept.

Letter from M/s. Otsuka to CIBRC



Otsuka Chemical Co., Ltd.
 1-1-1 Otsuka, Bunkyo-ku, Tokyo, 113, Japan
 TEL: 03-433-1111 FAX: 03-433-1111

To: CIBRC
 15, rue de la Loi, 1050 Brussels, Belgium
 (Institution of P.P.R.F. of the European Communities)

Dear Sirs,

Ref: Report of the Commission of the European Communities on the safety of Benfuracarb, 1987.

We, the Otsuka Chemical Company Limited, in the context of the registration of Benfuracarb in various countries, have been informed by you that the Commission of the European Communities has issued a report on the safety of Benfuracarb. We are pleased to note that the Commission has concluded that Benfuracarb is a Class I moderately hazardous product.

We are in full agreement with the Commission's findings and are pleased to note that Benfuracarb is a Class I moderately hazardous product.

If you need any more information, we are ready to supply it to you. We are sure that you will be satisfied with our service.

Yours faithfully,
 Otsuka Chemical Co., Ltd.
 President
 Otsuka Chemical Development Dept.

- Otsuka making this product for last 25 years
- Exported to Various Countries Like France, Spain, Italy, Korea and India
- Benfuracarb is Class I (moderately hazardous) product

Benfurcarb Status in Korea



- # Benfurcarb technical registered for Import from Japan By Dong bang Agro corporation
- # In Korea, Benfurcarb Technical Registered for Import
- # Registered 30% EC- Registered On citrus
- # Benfurcarb 3.0% Granule is Registered on Rice and other crops
- # Product is NOT RESTRICTED /BANNED IN KOREA

Letter from Korea To CIBRC



DONG BANG AGRO CORPORATION
1756 2 1756-2000 DONGBANG-RO, SUWON-CITY, KYONGGI-DO, KOREA

June 10, 2009

The Director General,
Central Bureau of Plant and Quarantine, Council of Agriculture, Forestry and Fisheries, Seoul, Korea

Dear Sir,

We are pleased to inform you that we have registered Benfurcarb 30% EC in Korea.

Benfurcarb 30% EC is a systemic insecticide which is highly effective against sucking insects such as aphids, whiteflies, and mealybugs.

Benfurcarb 30% EC is registered for use on citrus, rice, and other crops. It is highly effective against sucking insects such as aphids, whiteflies, and mealybugs.

Benfurcarb 30% EC is registered for use on citrus, rice, and other crops. It is highly effective against sucking insects such as aphids, whiteflies, and mealybugs.

Thank you for your kind attention.

Sincerely Yours,
Dong Bang Agro Corporation
Representative Director
Minsoo Kim

BENFURACARB 3.0% G REGISTRATION IN KOREA



RURAL DEVELOPMENT ADMINISTRATION
150, SUDBON-DONG, SUWON, REPUBLIC OF KOREA
C/O E. HANSEN & CO., SUWON

CERTIFICATE OF MANUFACTURE

We hereby certify that the following information has been submitted to the manufacturer of agricultural pesticides in accordance with the Agricultural Pesticides Act of the Republic of Korea and a certificate of compliance has been issued by the Ministry of Agriculture, Forestry and Fisheries.

Country of Origin	INDONESIA
Manufacturer	PT. HANSA, SUKSES, KOREA
Product Name	BENFURACARB 3.0% G
Active Ingredient	BENFURACARB
Formulation	GRANULES
Net Weight	100g

Your sincerely
Date: 2006. 12. 12
AIDM IN
DIRECTOR *Ahn Seok*
BGNALHRE, AGRICULTURE RESOURCES DIVISION
ADMINISTRATOR
RURAL DEVELOPMENT ADMINISTRATION



제출 일자: 2006. 12. 12
제출 번호: 2006-114호

농약 관리 과
농약 관리 팀

1. 농약명: 벤부라카רב 3.0% G
2. 농약 코드: 벤부라카רב 3.0% G
3. 농약 명칭: 벤부라카רב 3.0% G
4. 농약 명칭: 벤부라카רב 3.0% G
5. 농약 명칭: 벤부라카רב 3.0% G
6. 농약 명칭: 벤부라카רב 3.0% G
7. 농약 명칭: 벤부라카רב 3.0% G
8. 농약 명칭: 벤부라카רב 3.0% G
9. 농약 명칭: 벤부라카רב 3.0% G
10. 농약 명칭: 벤부라카רב 3.0% G

2006년 12월 12일
농약 관리 과장 *김종필*

Benfuracarb 3.0% label Claim in Korea



작물명	병해충명	농약명	농약코드	농약명칭	농약명칭
벼	벼멸구	벤부라카רב 3.0% G	000-0	벤부라카רב 3.0% G	벤부라카רב 3.0% G
포도	포도순채벌레	벤부라카רב 3.0% G	000-0	벤부라카רב 3.0% G	벤부라카רב 3.0% G
수박	수박순채벌레	벤부라카רב 3.0% G	000-0	벤부라카רב 3.0% G	벤부라카רב 3.0% G
코스모스	코스모스순채벌레	벤부라카רב 3.0% G	000-0	벤부라카רב 3.0% G	벤부라카רב 3.0% G

Usage on Rice, Grape, Watermelon and
Chrysanthemum in KOREA



Summary

Based on the information Available

- Benfuracarb is Not High Acute (LD50 is 213mg/kg b.w) and NOT Highly hazardous
- Benfuracarb is NOT BANNED /RESTRICTED in any of the countries in the world
- Benfuracarb is NOT BANNED /RESTRICTED in KOREA
- Benfuracarb Introduced in India only in Dec, 2004 (2 years Old Product).
- Benfuracarb is being well accepted by Indian Farmers.
- Benfuracarb is being used in Most of developed /Developing Countries in USA., Europe, Asia, Middle east, Africa etc



THANK YOU

8. Method and Usage (Benfuracarb GR) :

Crop	Pest	Application Time & Method	Usage (/10a)	Pre-harvest Interval		Enrolment
				Time	Applications	
Rice	Rice water weevil	nursery box treatment	60g/box	until early transplanting	A maximum of 1 applications	1999. 3. 11
Rice	Rice water weevil	water surface treatment	2kg	until early transplanting	A maximum of 1 applications	2001. 3. 28
Rice	Small brown planthopper	nursery box treatment	75g/box	until early transplanting	A maximum of 1 applications	2004. 4. 3
Rice	Rice stem maggot	nursery box treatment	60g/box	until early transplanting	A maximum of 1 applications	2006. 3. 28
Rice	Rice stem borer (first generation)	nursery box treatment	60g/box	until early transplanting	A maximum of 1 applications	2006. 3. 28
Grape	Grape phylloxera	soil treatment in stem	3kg	until 60 days of Pre- harvest	A maximum of 1 applications	2001. 3. 28
Watermelon	Cotton aphid	soil treatment	4kg	until transplanting	A maximum of 1 applications	1996. 12. 6
Watermelon	Green peach aphid	soil treatment	4kg	until transplanting	A maximum of 1 applications	1996. 12. 6
Chrysanthemum	Chrysanthemum aphid	soil treatment in stem	4g/stem	-	-	1998. 2. 25

Registered No. : 3-insecticide-114

Certificate of Pesticide Registration(manufacture)

6. Registrant : Dong Bang Agro Corporation

7. Registration Number : No. 3

8. Address : 1055-2, Namhyun-Dong, Kwanak-Ku, Seoul, Korea

9. Product Item : Benfuracarb GR

10. Trade Name : Sindrom

6. Active Ingredient & Content :

Ethyl-N-[2,3-dihydro-2,2-dimethyl benzofuran-7-yloxy carbonyl(methyl)-
aminothio]-N-isopropyl-β-alaninate ----- 3%

7. Target Crop / Pest : Rice·Rice water weevil, Rice·Small brown planthopper,
Grape·Grape phylloxer, Watermelon·Cotton aphid, Watermelon·Green peach aphid,
Chrysanthemum· Chrysanthemum aphid, Rice·Rice stem maggot ,
Rice· Rice stern borer(first generation)

8. Method and Usage : [next page]

9. Manufactory : 199, Byeokryong-Ri, Yangwha-Myeon, Fuyeo-Gun, Chungnam, Korea

10. Term of Validity : 2016. 12. 06.

This is to certify that the above-mentioned product has been registered in accordance with article 8 & 17 of the Agrochemicals Management Act

DATE : 2006. 03. 29.

ADMINISTRATOR
RURAL DEVELOPMENT ADMINISTRATION

Registered No. : 3-Insecticide-69

Certificate of Pesticide Registration(manufacture)

1. Registrant : Dong Bang Agro Corporation
2. Registration Number : No. 3
3. Address : 1055-2, Namhyun-Dong, Kwanak-Ku, Seoul, Korea
4. Product Item : Benfuracarb EC
5. Trade Name : Oncol
6. Active Ingredient & Content :
Ethyl-N-[2,3-dihydro-2,2-dimethyl benzofuran-7-yloxy carbonyl(methyl)=
aminothio]-N-isopropyl- β -alaninate ----- 30%
7. Target Crop / Pest : Citrus-aphid(Spiraea aphid)
8. Method and Usage : [next page]
9. Manufactory : 199, Byeokryong-Ri, Yangwha-Myeon, Puyo-Gun, Chungnam, Korea
10. Term of Validity : 2011. 12. 06.

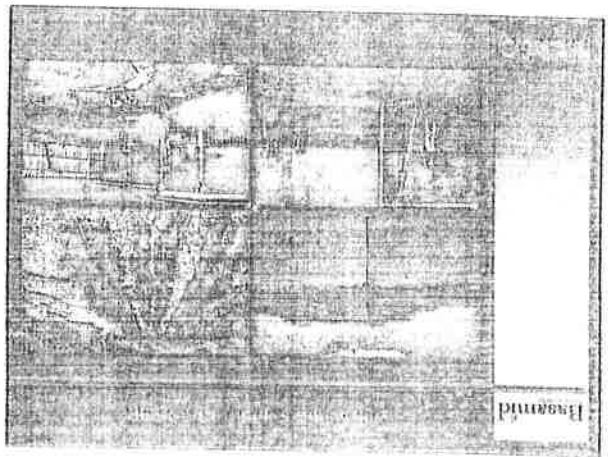
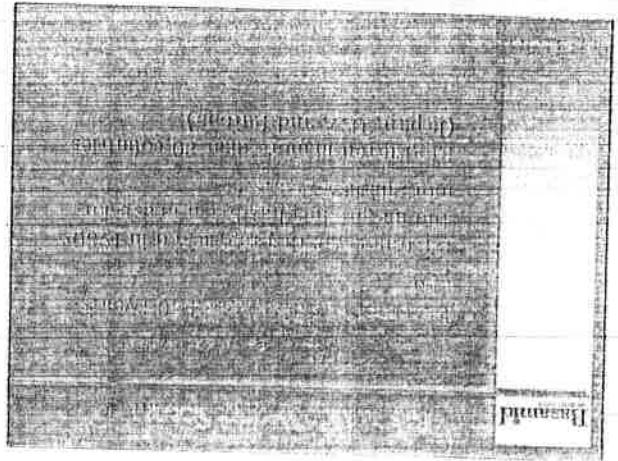
This is to certify that the above-mentioned product has been registered in accordance with article 8 & 17 of the Agrochemicals Management Act.

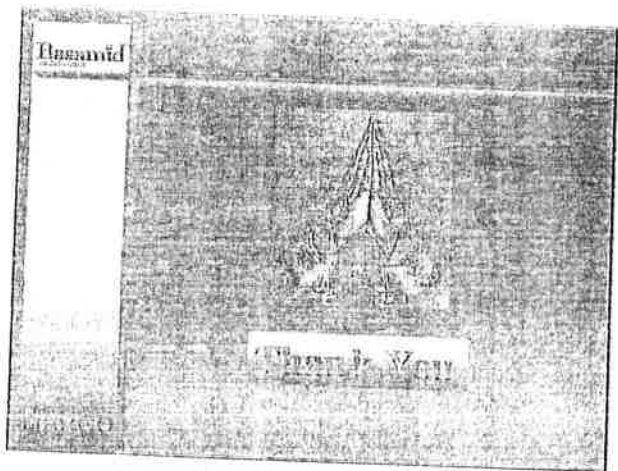
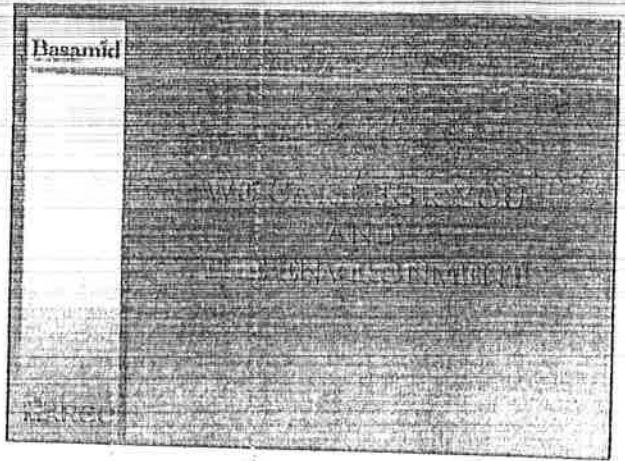
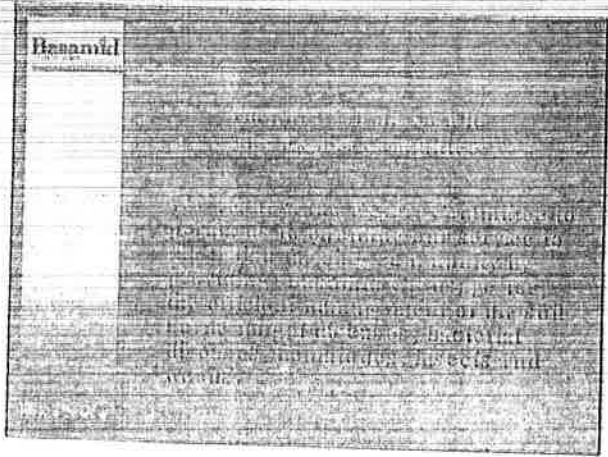
DATE : 2001. 12. 07.

ADMINISTRATOR
RURAL DEVELOPMENT ADMINISTRATION


8. Method and Usage (Benfuracarb EC) :

Crop	Pest	Application Time & Method	Dilution	Pre-harvest Interval		Enrollment
				Time	Applications	
Citrus	aphid(Spiraea aphid)	when pests first appear (Avoid blooming period)	X 1,000	until 30 days of Pre-harvest	A maximum of 3 applications	1986. 3. 8





DIFLUBENZUROM 25 WP
INSECTICIDE (MOULTING
INHIBITOR)

Chemtura

Registered in India for pest
control in agriculture crops
and Mosquito larvae control

All aspects of the molecule has been thoroughly reviewed by the Directorate of Plant Protection, Quarantine & Storage (GIB & RC) and approved for its use against

caterpillar pests of Cotton and Groundnut (Tobacco caterpillar, Bollworm and leaf Webber)
@ 300 - 400 g/ha

against three species of mosquito larvae (*Aedes*, *Anopheles* & *Culex*)

Clear surface water - 200g/ha; Polluted surface water - 400g/ha; sewage pits, soak pits, latrines, septic tanks - 4 g in 1000 l water

It is an Insect Growth Regulator (IGR) emerging as a most effective tool against field crop caterpillar pests and Mosquito larvae control all over the world

Specific in mode of action, acts as chitin inhibitor (interferes with chitin deposition) and very safe to non target beneficial insects

Registered in over 50 countries around the world including USA and EU

Toxicological data has been reviewed by WHO/FAO in 2001 and declared safe

Ref. Diflubenzuron - JMPR 2001 (Doc. Ref. FAO 167 page 43)

Data available at UN International Programme on Chemical Safety, IPCS

On the basis of the data from supervised residue trials on various crops have been accepted by WHO (Panel of JMPR 2001) established Maximum Residue Limit (MRL) on various crops

Cotton 0.2 ppm, Cabbage 1 ppm, Citrus 1 ppm

Apple 1 ppm, Soybean 0.1 ppm & Tomato 1 ppm

Chemtura

Diflubenuron has been classified as 'unlikely to present an acute hazard in normal use' by WHO

The LD50 oral > 4000 mg/kg bw in mice and rats

Dermal LD50 of > 10 000 mg/kg bw in rats

Inhalation with an LC50 > 2.8 mg/l of air No clinical signs were seen in these studies

ADI of 0-0.02 mg/kg bw has been reestablished based on the NOAEL for haematological effects of 2 mg/kg bw per day in the 2-year studies in rats and the 52-week study in dogs

Ref. Diflubenuron - JMPR 2001
(Doc. Ref. FAO 577)

Diflubenzuron has not been registered in Belize for any use

Belize does not have formal registration system
Individual companies obtain local permits to import products for
specific use

Our company has no knowledge of such permitted use
restriction of Diflubenzuron use
Incorrect entry

As the JMPR is considered the superior UN body for conduct of evaluation of studies
and the review, the documents may be taken as evidence of the safety of this product and
it is proposed that there is no need for action on this compound

Chemtura

WELCOME

SUMITOMO CHEMICAL INDIA PVT. Ltd.

Fenpropathrin

Review Committee Presentation : Dec.14,2008, New Delhi
(Dr. S. Bedi / Mr.M.Mouchi)

FENPROPATHRIN - The Product

[(RS)-α-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate.]

- Belongs to Synthetic Pyrethroid Group.
- Insecticide (Lepidoptera and White fly) and Acaricide (broad spectrum), in global market for more than 2 decades.
- Registered in 30 countries on variety of crops. In India registered for use in Cotton, Vegetables and Tea.
- Have both knock down and residual control.
- Locally manufactured, for export and domestic market (growing).
- No Toxicity and Environmental issues.
- Ideal combi partner for IGRs

Notification - Review in India

References Quoted:

- Restriction in Korea due to Toxicity to Fish and Honey bee.
- Not allowed in Malaysia due to hazardous nature

Reality : Follows

Registered in Malaysia

- Date of registration : July 2005
- Registration no. : LRMP.RI/6036
- Formulation : 10% SC

• Conditions laid :-

- Must follow all conditions and guidelines issued by the Pesticide board from time to time.
- This pesticide can not be advertised on any media without approval from pesticide board.
- This pesticide must be used per the latest label approved by pesticide board.

Status in Korea

- Date of registration : July 1997
- Business Registration no. : Manufacturer no.3
- Formulations : 5% WP

• Condition laid :- The general precautionary statement applicable for all commonly used Synthetic Pyrethroid products in Korean market.

Caution no.	Caution
1	As this product is toxic to silkworm, do not apply this product near mulberry field, and take care not to go into fields with equipment for silkworm rearing.
2	As this product is toxic to honey bees, do not apply this product or allow it to drift to blooming period.
3	As this product is classified as fish toxicity level 1 (LD50 for Carp, (fish) - 0.5mg/L), do not apply this product in the area where applied product is drifted by wind or directly flowed out with rain water to fish breeding ponds, reservoirs, spots for water supply and sea area.

Precautionary Guideline for SP products in Korean Market

Product	Caution no.		
	1	2	3
Deltamethrin	O	O	O
Lambda-cyhalothrin	O	O	O
Difenthrin	X	O	O
Fenpropathrin	O	O	O
Cyfluthrin	O	O	O
Cypermethrin	O	O	O
Alpha cypermethrin	O	O	O
Fenvalerate	O	O	O
Bioleproax	O	O	X

O : Applicable

X : Not applicable

Korea & Malaysia : Current Business

Sumitomo Chemical company is happy to state that both in Malaysia & Korea, Fenpropathrin (Danitol) use is consistent and no specific issue of Tox & Environ. nature has been brought to notice by the authorities.

Fenpropathrin - Toxicity Rating

Toxicity classification	Rating/Class	Description / warning label
India : CIB-RC	Highly toxic	Highly toxic - Poison Toxicity Triangle : Yellow
WHO	II	Moderately hazardous
EPA	II	Moderately toxic - Warning

Toxicity to Fish and Honey bee

Comparison statement follows, reveals that the product has a better profile than many insecticides used in India.

Comparative Fish toxicity data of pesticides (LC50 mg/l)

Name of the product / Fish spp	Rainbow trout	Bluegill sunfish
**Bifenthrin (06h)	0.0015	0.0036
**Lambda-cyhalothrin (06h)	0.0030	0.0021
**Cyhalothrin (06h)	0.0084	-
**Cyfluthrin (06h)	0.0008-0.0028	0.0018
**Cypermethrin (06h)	0.0009	0.0037 (bluegill sunfish)
**Deltamethrin (06h)	0.00091	0.0014
**Fenpropathrin (48h)	*0.00246 (Thapsi Stoccamble) Fenpropathrin 30EC (5h)	0.00195
**Alpha cypermethrin (06h)	0.0028	-
**Fenvalerate (06h)	0.0030	-
**Mibumosin (06h)	0.0045	Carp 0.017
**Quinolphos (06h)	0.005	Carp 3.63
**Fenpyroximate (48h)	Carp 0.008	-
**Chlorpyrifos (06h)	0.007-0.081	0.002-0.010
**Profenofos (06h)	0.03	0.3 Crucian carp 0.08
**Fipronil (06h)	0.218	0.085

Ref: **The Pesticide Manual - 12th Edition

* Own generated data

Comparative Honey bee toxicity (date of pesticides)		
Name of the product	Oral LD50 (µg/kg)	Contact LD50 (µg/m ² /sec)
**Spinosad (0.5%)		0.0029
Emamectin benzoate		0.0016
**Difenthrin	0.1	0.01432
**Cypermethrin	0.036	0.03
Imidacloprid	0.002	0.024
**Thiamethoxam		0.024
**Bifenthrin	0.10	0.025
**Alpha cypermethrin		0.050
**Deltamethrin	0.078	0.051
**Thiopyriths	0.080	0.070
Profenofos		0.102
**Fenpropathrin		0.02
Fenpropathrin 30EC		0.12
**Oxalaphos	0.07	0.17
**Chlorfenvinpyr		0.2
**Fenvalerate		0.23
**Lambda-cyhalothrin	0.032	0.60

Ref.: **The Pesticide Manual, 15th Edition

* Own generated data

Global registration status of product		
Sl No	Country	Crops
1	India	Cotton, Tea, Chilli, Okra, Brinjal
2	Japan	Apple, Plum, Citrus, Pear, Grapes, Peach, Loquat, Persimmon, Tea, Pepper, Strawberries, Watermelon, Aubergina, Tomato, Cucumber, Melon, Pumpkin, Kidney bean, Ornamental.
3	USA	Apple, Pear, Citrus, Cotton, Grapes, Broccoli, Cabbage, Cauliflower, Cucurbit, Peanuts, Strawberry, Tomato, etc. both topical & aerial application.
4	Mexico	Cotton, Tomato, Melon, Cucumber, Grape, etc.
5	Brazil	Cotton, Apple, Coffee, Citrus, Rice, Chrysanthemum.
6	Korea	Apple, Pear, Citrus, Persimmon, Watermelon, Tomato.
7	Malaysia	Mango, Guava, Citrus, Tomato, Chilli, Pomelo.

Other countries: Vietnam, Thailand, Indonesia, Cambodia, Bangladesh, China, Turkey, Iraq, Iran, Saudi Arabia, Egypt, Kuwait, Syria, South Africa, Kenya, Costa Rica, Guatemala, Honduras, Panama, Colombia, Ecuador, Peru, Argentina.

Summary

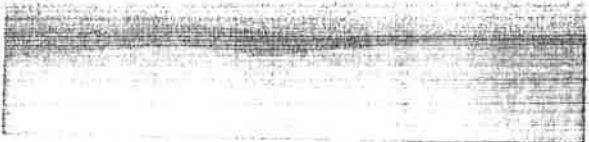
- Fenpropathrin is registered in India. Thoroughly evaluation of attributes / information on different regulatory parameters have been done.
- Registered globally and in commercial use on several crops.
- There is no restriction specifically attributable to the nature of the product as such, those in "Korea" and "Malaysia" are very general.
- Useful tool to manage economically important insect pests: Whitefly, Borers, Flies etc
- Sunilomo Chemical marketing operations are based on quality adherence and Product Stewardship. No resistance case is on record.
- No Toxicological and environmental issues have been reported anywhere in the world.
- Product acceptability is high in all geographies in India.

Submissions

In view of the facts known / presented,
 may we request
 the Esteemed Committee Members
 To allow,
 "use of the product in India"
 As per the existing approval.

12

WISH YOU
HAPPY & PROSPEROUS NEW YEAR





Bayer Crop Science

IPRODIONE
General Overview

Mr. Kishor Nahar
Head – Registration & Regulatory Affairs
Bayer Crop Science India

Review Meeting/ Presentation on 14th Dec. 09/Presenter : Kishor Nahar • Slide 1

General Overview

Registration Status in India

- Product is registered and being sold in India since 1995.

Formulation	Approved uses	Target Diseases
Iprodione 50% WP (Rovral 50 WP) 1995	Rice	Sheath Blight & Blast
	Tomato	Early Blight
	Rapeseed Mustard	Alternaria Blight
Iprodione 25% + Carbendazim 25% WP (Quintal 50 WP) 2001	Rice	Sheath Blight

Review Meeting/ Presentation on 14th Dec. 09/Presenter : Kishor Nahar • Slide 4

Concerns raised by the Review Committee

The following concerns raised would be addressed by our experts :

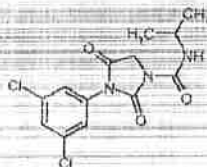
"It is banned in Denmark because the product is assessed to be

- carcinogenic in category 3 and harmful to reproduction (category 3).
- harmful to reproduction of wild birds and mammals and therefore, seriously damaging the health and environment."

"As per the data available, the consumption is 0.0 MT."

Review Meeting/ Presentation on 14th Dec. 09/Presenter : Kishor Nahar • Slide 5

General Overview

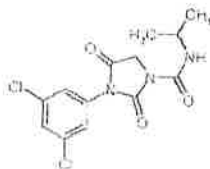


IPRODIONE (ROVRAL®)

- Fungicide discovered by Bayer CropScience (erstwhile Rhône-Poulenc) in 1971.
- First registration in 1975 in France.
- Iprodione is a contact fungicide belonging to a unique the cyclic imide family.
- It is effective against spores and mycelium of a number of parasitic fungi and exhibits both protectant and some eradicant activity.

Review Meeting/ Presentation on 14th Dec. 06/Presenter : IGshor Nehar • Slide 2

General Overview



IPRODIONE (ROVRAL®)

- A very popular and versatile Fungicide used in various formulations as a spray, seed treatment as well as post-harvest treatment worldwide
- It is specially effective against Benzimidazole resistance fungal pathogens - *Alternaria*, *Botrytis*, *Fusarium*, *Monilinia*, *Rhizoctonia*, *Sclerotium*, etc.
- Presently registered in over 80 countries worldwide, including Australia, Brazil, Canada, EU countries, Japan, S. Africa and U.S.A. for control of various diseases in the field

Review Meeting/ Presentation on 14th Dec. 06/Presenter : IGshor Nehar • Slide 3

Concerns raised by the Review Committee

The following concerns raised would be addressed by our experts :

"It is banned in Denmark because the product is assessed to be

- carcinogenic in category 3 and harmful to reproduction (category 3).

- harmful to reproduction of wild birds and mammals and therefore, seriously damaging the health and environment."

"As per the data available, the consumption is 0.0 MT."



Paracetamol

Banned in Denmark (1987) because
of evidence of "assesssed to be carcinogenic in certain
and harmful to the reproduction (rep est.3) and the
products are, therefore, damaging to health"

Dr. Remi Bars
Toxicologist, BCS France

Classification of Iprodione in Europe

Carcinogenicity

- European Chemicals Bureau (ECB) final decision in 1999:
Category 3
- The classification of Iprodione in Category 3 carcinogen is based on a limited number of histopathological changes that were observed in long-term studies conducted in mice and rats.
- This category is the minimal classification applied in Europe when there is only limited evidence of oncogenicity.
- Consumer risk assessment without any additional safety factor (EU and JMPR)

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Remi Bars • Slide 7

Classification of Iprodione in Europe

Reproduction

- During the classification and labelling process the Danish Environmental Protection Agency expressed some concerns about the potential effects of Iprodione on fertility.

Proposed classification: Category 3 for reproduction
- The overall review of data from reproduction, sub-chronic, chronic studies focusing on reproductive end-points and a large set of additional in vitro and in vivo mechanistic studies provided strong evidence that Iprodione has no effects on the reproductive function.
- ECB decision (1999): Not to classify Iprodione for reproduction in EU

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Remi Bars • Slide 8

Results from the Two-generation Reproduction Study (Hazleton, 1991)

0, 300, 1000 or 3000 ppm (↓ to 2000 ppm at time of 1st mating of F1)

○ Results

○ **No effect at any dose level on**

- fertility (male and female)
- mating indices
- gestation indices/length of gestation
- sex determination at birth (sex ratio)
- pups external malformation
- gonads, prostate, seminal vesicles coagulating glands, epididymides of parental animals

Marked parental toxicity at >1000 ppm

○ Conclusion:

no specific effects on the reproductive parameters and function

Review Meeting/ Presentation on 14th Dec. 08/Presenter: Remi Bars • Slide 9

Results from a Developmental study with peri-natal Administration

Iprodione administered at 100 mg/kg/day to

- pregnant SD dams from
- gestation day 14 to day 3 of lactation.

○ Parameters examined were organ weights and histopathology on

- prostate, seminal vesicle, testis, epididymis, liver... etc.,
- anogenital distance, male internal and external abnormalities such as retained nipples, vaginal pouch, hypospadias

- no maternal or fetal endocrine toxicity
- no alteration in male rat sexual differentiation

Gray JR, L.E., Wolf C., Lambright C., Mann P., Price M., Cooper R.L., Jetby J.
Toxicology and Industrial Health (1989) 15, 94-118.

Review Meeting/ Presentation on 14th Dec. 08/Presenter: Remi Bars • Slide 10

Summary from Developmental and Reproduction Studies

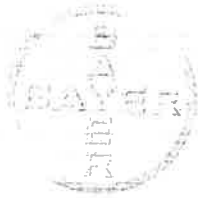
- Reproduction and developmental studies conducted
 - at high toxic dose levels (exceeding the MTD)
 - with full in utero exposure
 - for several consecutive generations or perinatal exposure
- no evidence of alteration in reproductive parameters or reproductive function.

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Remi Bars • Slide 11

Overall summary

- Minimal classification for carcinogenicity (category 3) in Europe to account for the limited relevance to humans of oncogenicity observed in laboratory animals following life time treatment at high dose levels.
- No classification of Iprodione for reproductive toxicity in the EU
- Iprodione included in EU Annex I in 2003
- Therefore ban in Denmark not valid anymore

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Remi Bars • Slide 12



Dr. Raimund Grau

Dr. Raimund Grau
Global Product Safety Manager, BCS Germany

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 13

Use pattern of Rovral WP 50 in India

Crop	Common name of disease	Application rate a.i. [kg/ha]	Application rate product [kg/ha]	Number of applications	Application interval [days]
Rapeseed mustard	Alternaria blight	1.125 - 1.5	2.25 - 3.0	2 - 3	10 - 15
Rice	Sheath blight	1.125	2.25	2 - 3	10 - 15
Tomato	Early blight	0.75	1.5	2 - 5	10 - 15

Review Meeting/ Presentation on 14th Dec. 06/Presenter : Raimund Grau • Slide 14

Risk assessment for wild birds and mammals

- Ecotoxicological Risk Assessment
- US-EPA 1986 (Urban & Cook)
- $RQ = EEC / NOEC$

RQ = risk quotient

EEC = estimated exposure concentration

NOEC = no observed effect concentration

- If $RQ < 1$ no presumption of risk



Review Meeting/ Presentation on 14th Dec. 06/Presenter : Raimund Grau • Slide 15

Long-term toxicity of Iprodione to birds

○ Bobwhite quail

● NOEC 300 ppm

● Indications of food avoidance at higher exposure levels



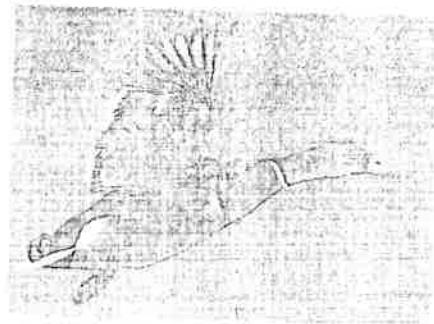
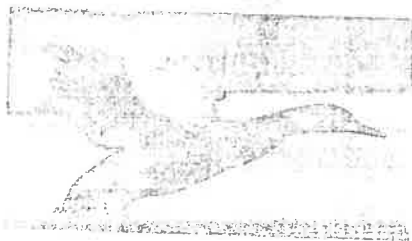
Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 16

Long-term toxicity of Iprodione to birds

○ Mallard duck

● NOEC >1000 ppm

● No effects on body weight, feed intake, survival and reproduction



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Long term toxicity of Iprodione to birds

○ Chickens

NOEC 1000 ppm based on body weight loss and egg production

○ Substrate case

NOEC 1000 ppm based on egg production and body weight

○ Ducks

NOEC 1000 ppm based on egg production and body weight

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 18

Long term toxicity of Iprodione to mammals

○ Rat

NOEC 300 ppm

Based on effects on pup weight and viability at maternally toxic doses



○ Conclusions

No evidence that Iprodione is harmful to reproduction of wild mammals

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 19

Ecotox Risk Assessment (RO = EEC / NOEC)

Ecotoxicological Endpoints (NOEC's)

- NOECs for wild birds and mammals taken from endpoint list of EU-Review (2003)
- Lowest NOEC for long-term exposure / reproduction
 - birds 300 ppm
 - mammals 300 ppm

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 20

Exposure assessment (RQ = EEC / NOEC)

- EEC = RUD x application rate x no. of appl.
- Residue per Unit Dose (RUD, generic)
 - Residues (in mg/kg or ppm) expected after application of 1 kg a.i./ha
 - **Hoerger, F. and Kenaga, E.E.**, Pesticide Residues on Plants: Correlation of Representative Data as a Basis for Estimation of Their Magnitude in the Environment, Environmental Quality and Safety, I, 9 - 28, 1972

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 21

Exposure assessment (RQ = EEC / NOEC)

- EEC = RUD x application rate x no. of appl.
- Residue per Unit Dose (RUD, generic)
 - Residues (in mg/kg or ppm) expected after application of 1 kg a.i./ha

Crop	Plant category	Residues immediately after application		Residues 6 weeks after application		Arithmetic mean of upper limits from immediately and 6 weeks after application
		Upper limit	Typical limit	Upper limit	Typical limit	
Rice	Grass	98	82	18	1-5	58
Repeated mustard	Leaves and leafy crops	112	31	18	< 1	65
Tomatoes	Fruits	6.2	1.3	1.3	< 0.2	0.7

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 22

Exposure assessment (RQ = EEC / NOEC)

- EEC = RUD x application rate x no. of appl.
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Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 23

Exposure assessment (PO = EEC / NOEC)

Average residues / no degradation

$$EEC = RUD \times \text{application rate} \times \text{no. of appl.}$$

Crop	Plant category	Residues immediately after application		Residues 6 weeks after application		Arithmetic mean of upper limits from immediately and 6 weeks after application
		Upper limit	Typical limit	Upper limit	Typical limit	
Rice	Grass	98	32	18	1-5	58
Rapeseed mustard	Leaves and leafy crops	112	31	18	< 1	66
Tomatoes	Fruits	6.2	1.3	1.3	< 0.2	0.7

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Reimund Grau • Slide 24.

Exposure assessment (PO = EEC / NOEC)

Average residues / no degradation

$$EEC = RUD \times \text{application rate} \times \text{no. of appl.}$$

Crop	RUD (ppm per kg/ha)	Crop	Plant category	Residues immediately after application		Residues 6 weeks after application		Arithmetic mean of upper limits from immediately and 6 weeks after application
				Upper limit	Typical limit	Upper limit	Typical limit	
Rice	82	Rice	Grass	98	32	18	1-5	58
Rapeseed mustard	31	Rapeseed mustard	Leaves and leafy crops	112	31	18	< 1	66
Tomatoes	1.3	Tomatoes	Fruits	6.2	1.3	1.3	< 0.2	0.7

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Reimund Grau • Slide 25

Exposure assessment (RO = $\frac{EEC}{NOEC}$)

Average residues / no degradation

$$EEC = RUD \times \text{application rate} \times \text{no. of appl.}$$

Crop	RUD (ppm per kg/ha)	Max. application rate (kg/ha)	Max. no. of applications	EEC (ppm)
Rice	82	1.125	3	276.8
Rapeseed mustard	31	1.5	3	139.5
Tomatoes	1.3	0.75	5	4.9

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 26

Exposure assessment (RO = $\frac{EEC}{NOEC}$)

Max. residues / degradation between applications

$$EEC = RUD \times \text{application rate} \times \text{no. of appl.}$$

Crop	Plant category	Residues immediately after application		Residues 6 weeks after application		Arithmetic mean of upper limits from immediately and 6 weeks after application
		Upper limit	Typical limit	Upper limit	Typical limit	
Rice	Grass	98	82	18	1-5	58
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Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 27

Exposure assessment (RQ = EEC / NOEC)

Max. residue / degradation between applications

$$EEC = RUD \times \text{application rate} \times \text{no. of appl.}$$

Crop	RUD (ppm per kg/ha)	Crop	Plant category	Residues immediately after application		Residues 6 weeks after application		Arithmetic mean of upper limits from immediately and 6 weeks after application
				Upper limit	Typical limit	Upper limit	Typical limit	
Rice	58	Rice	Grass	88	82	13	1.5	0.5
rapeseed mustard	63	Rapeseed mustard	Leaves and leafy crops	112	31	13	< 1	0.5
Tomatoes	0.7	Tomatoes	Fruits	6.2	1.3	1.3	< 0.2	0.7

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Reimund Grau - Slide 28

Exposure assessment (RQ = EEC / NOEC)

Max. residue / degradation between applications

$$EEC = RUD \times \text{application rate} \times \text{no. of appl.}$$

Crop	RUD (ppm per kg/ha)	Max. application rate (kg/ha)	Max. no. of applications	EEC (ppm)
Rice	58	1.125	3	195.8
rapeseed mustard	63	1.5	3	292.5
Tomatoes	0.7	0.75	5	2.6

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Reimund Grau - Slide 29

Risk assessment (RQ = EEC / NOEC)

○ Risk Quotient: No risk if RQ < 1

Crop	EEC (ppm)	NOEC (ppm)	RQ	Conclusion
Rice	276.8	300	0.92	No risk
Reprocessed mustard	139.5	300	0.47	No risk
Tomatoes	4.9	300	0.02	No risk

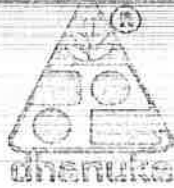
Crop	EEC (ppm)	NOEC (ppm)	RQ	Conclusion
Rice	195.8	300	0.65	No risk
Reprocessed mustard	292.5	300	0.98	No risk
Tomatoes	2.6	300	0.01	No risk

Review Meeting/ Presentation on 14th Dec. 00/Presenter: Raimund Grau • Slide 30

Summary

- Even under worst-case assumptions for use of Iprodione in India
 - maximum application rate
 - maximum number of applications
 - no degradation / dissipation between applications or
 - maximum residue levels
- Risk Quotients (RQ) are all below 1
- **no chronic risk, including reproduction, to wild birds and mammals**

Review Meeting/ Presentation on 14th Dec. 00/Presenter: Raimund Grau • Slide 31



DHANUKA GROUP

WELCOMES

YOU

KASUGAMYCIN

A. A systemic antibiotic, *Kasugamycin* has been developed through a culture filtrate of the actinomyces classified as *Streptomyces kasugaensis* is highly effective against rice blast caused by *Pyricularia oryzae*.

In India *Kasugamycin* is Registered for the control of Rice Blast disease only with its preventive and curative action against the fungus *Pyricularia oryzae*.

KASUGAMYCIN

2. Worldwide Registration status of *Kasugamycin* for the control of Rice Blast disease.

1. Brazil	6. Indonesia	11. Jamaica
2. Japan	7. Bangladesh	12. Dominica
3. Korea	8. Sri Lanka	13. Colombia
4. Taiwan	9. Mexico	14. Venezuela
5. China	10. Central America	15. Ecuador

3. Worldwide Registration status of *Kasugamycin* on other crops

Crop	Disease	Country
Sugar beet	Cercospora leaf spot (<i>Cercospora beticola</i>)	Japan, Central America
Chinese cabbage	Bacterial leaf spot (<i>Pseudomonas maculicola</i>)	Taiwan
Coffee	(<i>Pseudomonas</i> sp.)	Central America
Tomato	Leaf mold (<i>Cladosporium fulvum</i>)	Central America, Chile
Cucumber	Angular leaf spot (<i>Pseudomonas lachrymans</i>) Anthracnose (<i>Colletotrichum lagenarium</i>)	Central America, Chile, Hungary
Carrot Potato	Bacterial soft rot (<i>Erwinia carotovora</i>)	Brazil, Uruguay
Apple	Scab (<i>Venturia inaequalis</i>)	Greece
Green beans	Halo blight (<i>Pseudomonas phaseolicola</i>)	Hungary

KASUGAMYCIN

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3. Worldwide Registration status of Kasugamycin on other crops

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Sugar beet	Carabopers leaf spot (<i>Carabopers-levicola</i>)	Japan, Central America
Chinese cabbage	Bacterial leaf spot (<i>Pseudomonas maculicola</i>)	Taiwan
Coffee	(<i>Pseudomonas</i> sp.)	Central America
Tomato	Leaf mold (<i>Cladosporium fulvum</i>)	Central America, Chile
Cucumber	Angular leaf spot (<i>Pseudomonas lacinianica</i>) Anthracnose (<i>Colletotrichum lagenarium</i>)	Central America, Chile, Hungary
Carrot	Bacterial soft rot (<i>Erwinia carotovora</i>)	Brazil, Uruguay
Potato	Scab (<i>Venturia hirsuta</i>)	Greece
Green beans	Halo blight (<i>Pseudomonas phaseolicola</i>)	Hungary

DETAILED EXPLANATION RELATING TO CONCERNS NOTICED DURING THE 9TH MEETING OF THE EXPERT GROUP ON KASUGAMYCIN

The Expert Group has noticed concerns viz:

- (1) The product is severely restricted in Belize. Use allowed for control of Rice blast only.
- (2) Source of toxicology information submitted by M/e Dhanuku Pesticides Ltd., has not been indicated.
- (3) Consumption data not available.

Pointwise replies are given hereunder:-

Cont. 2

- 1) The Product is severely restricted in Belize. Use allowed for control of Rice blast only.

Belize is a small country having a geographical area of 22966 sq. km, out of which total agricultural area is 0.99 lac hectares. The major crops are wheat, maize and rice which are replanted after each year harvest and the permanent crops are citrus, coffee and rubber.

contid.3

Reasons for restrictions for use in Belize for the control of rice blast only are not known. However, the following may be the reason for restrictions;

Kasugamycin is a systemic fungicide and bactericide effective in the control of fungal and bacterial diseases, affecting rice, vegetables and fruits. The product has been found most effective against rice blast disease. Therefore, its registration seems to have been sought for the control of rice blast disease only in Belize. It can be attributed that Kasugamycin is restricted for its use in rice crop for the control of blast disease only. Merely inclusion of Kasugamycin

contd.4

7

In the list information on banned / severely restricted pesticides based on consolidated list of products whose consumption and or sale have been banned, withdrawn, severely restricted or not approved by the Governments does not mean that the product is restricted because of its efficacy or safety to human health, environment etc.

contd.5

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2) Source of toxicology information submitted by M/s Dhanuka Pesticides Ltd., has not been indicated.

Regarding source of toxicological information on Kasugamycin, earlier submitted was taken from the Technical Bulletin of M/s Hokko Chemical Industry Co. Ltd., Tokyo Japan. Copy of the Technical Bulletin and the relevant information duly authenticated have been submitted to CIB & RC.

The same is reproduced hereunder:-

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KASUGAMYCIN



HOKKO CHEMICAL INDUSTRY CO., LTD.
TOKYO JAPAN

10

Toxicological information

Minimal toxicity

1. Acute toxicity

LD₅₀ in mg/kg

Route	Species (sex)	
	Mouse (Male & female)	Rat (Male)
Oral	20,500	22,000
Intravenous	4,000	5,200
Intraperitoneal	10,000	12,000
Subcutaneous	12,000	17,000

Reference: 1. Minimum lethal dose of table salt

Rat Oral 8,000 mg/kg

Intraperitoneal 5,000 mg/kg

2. Minimum lethal dose of sugar (saccharose)

Dog oral 8,000-12,000 mg/kg

This shows that Kasugamycin is even safer than Salt & Sugar

2. Sub-acute toxicity

2.1. Feeding study (3 months)

The study was conducted on rats and mice fed standard ration mixed with Kasugamycin. As a result, the maximum no-effect level was estimated as 100 mg/kg/day.

2.2. Intramuscular injection study (125 days)

Duration of intramuscular injection with Kasugamycin at 200 mg/kg/day for 125 days did not cause any particular ill-effect to dogs.

The no-effect level was more than 200 mg/kg/day.

2.3. Subcutaneous injection study (6 months)

When Kasugamycin was subcutaneously injected to rats at a dose of 200 mg/kg/day for weeks, anorexia was observed 5 ~ 6 days after the beginning of the administration, but almost recovered within 3 ~ 4 weeks. This anorexia slightly affected body weight gain. Increase of water consumption was also observed up till anorexia was recovered. No other adverse effect due to the treatment was observed.

3. Chronic toxicity

3.1. Two year chronic oral toxicity study in albino rats
Two years of feeding Kasugamycin to albino rats at dietary levels of 200, 1,000 and 5,000 ppm has

Revealed no abnormalities related to the treatment in the following parameters except the increase of changes in the kidneys at the 5,000 ppm dose of both sexes. The no-effect level is 40.4 mg/kg (1,000 ppm)

- Body weight
- Food consumption
- Water consumption
- Mortality and reactions
- Hematologic studies

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Clinical Chemistry

Urinalysis

Pathologic studies: Necropsy findings
Organ weight and ratio data
Histopathologic studies

3.2. Two year chronic oral toxicity study in beagle dogs

Two-year oral administration of Kasugamycin to purebred beagle dogs at dietary levels of either 200, 800 or 4,000 ppm has revealed a lower body weight gain for female fed 4,000 ppm.

This shows that Kasugamycin is safe.

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No treatment-related abnormalities were observed in the following parameters. The no-effect level is 21.3 mg/kg (500 ppm)

- Food consumption
- Food efficiency
- Water consumption
- Behavioral reactions
- Mortality
- Hematologic studies
- Blood chemistry
- Urinalysis
- Organ weights
- Gross pathologic studies
- Histopathologic studies

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3.3. Multiple generation reproduction study in rats

A multiple generation reproduction study was conducted on rats fed diets containing either 100 or 1,000 ppm kasugamycin.

There were no deaths related to the dietary exposure, and no abnormalities were noted in each tests on reproductions and lactations.

No specific changes were noted in the body weight gains, hematological and biochemical studies, organ weights and histopathological examinations.

The no-effect level is more than 60 mg/kg (more than 1,000 ppm)

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4. Special studies

4.1. Mutagenicity study

Kasugamycin was found to be negative in all the following microbial tests:

- (1) Rec-assay using two strains of *Bacillus subtilis*;
- (2) Reverse mutation tests with or without a metabolic activation system, using *Escherichia coli* WP2 her and five strains of *Salmonella typhimurium* TA series;
- (3) Host-mediated assay using *S. typhimurium* G46 in mice.

4.2. Teratogenicity study

Kasugamycin was fed to the pregnant rats in concentration of 100 or 1,000 ppm in the food, no changes in the number of fetuses alive and the ratio of resorption were noted in all treated groups.

In the skeletal examination, one fetus (1.2%) in the 100 ppm group showed the fusion of cervical arch and the deformity of corpus thoracis and one (1.4%) in the 1,000 ppm group showed the fusion of cervical arch. In the development degree of ossification, however, no significant differences were noted between groups. No abnormalities were noted in any inert organs. The no-effect level is more than 100 mg/kg/day (more than 1,000 ppm)

This shows that Kasugamycin is safe.

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4.3. Carcinogenicity study

Kasugamycin was fed to groups of albino rats at dietary levels of 200, 1,000 or 5,000 ppm for twenty-four months. None of neoplasms observed could be attributed to the effects of the test material. The type and incidence of neoplasms observed were considered normal for rats of this age, sex and strain.

4.4. Respiration and blood pressure

Kasugamycin was intravenously injected in cats, male, at each dose of 25, 50, 100 and 200 mg/kg, and the respiration and blood pressure were measured with kymography. Any adverse effect was observed neither in respiration nor in blood pressure.

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4.5. Eye irritation

When 0.1 ml of 40% Kasugamycin saline solution was instilled on eyes of rabbits, no irritation was observed.

Toxicity to fish, honey bees and birds

1. Toxicity to fish

Carp, Daphnia: TL₅₀ (48 hours) values are more than 40 ppm.

Guppies, Goldfish: Caused no toxic result when these were kept in the aqueous solution of Kasugamycin at a concentration of 1,000 ppm.

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2. Toxicity to honey bees

As the results of the study carried out by method of direct spraying of the water solution containing 80 ppm Kasugamycin to 60 bees in total tested, there was found no death of the bees considered an effect of Kasugamycin treatment in a period of 72 hours after treatment.

3. Toxicity to birds

Kasugamycin was administered orally to male quails at a dose of 4,000 mg/kg, and no death or no abnormal behavioral reactions were noted. LD50 to quails, therefore, is more than 4,000 mg / kg.

In addition, information on toxicology as published in the Pesticide Manual (14th edition, 2006) is also given hereunder for consideration by the Expert Group.

MANMALIAN TOXICOLOGY:

Acute oral LD ₅₀ for mice -	> 5000 mg / kg.
Acute percutaneous LD ₅₀ for rabbits -	> 2000 mg / kg. Non-irritating to eyes and skin
Inhalation LC ₅₀ (4 h) for rats -	> 2.4 mg / l.
NOEL (2 y) for rats for dogs	300 mg / kg. diet 800 mg / kg. Diet
Non-mutagenic and non-teratogenic in rats, and without effect on reproduction.	
Toxicity class - WHO (p.I.)	U - (Product unlikely to present acute hazard in normal use)
EPA (formulation)	IV

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ECOTOXICOLOGY

Birds Acute oral LD50 for male Japanese quail	>4000 mg /kg.
Fish LC50 (48 h) for carp and goldfish	> 40 mg / l.
Daphnia LC50 (6 h)	> 40 mg / l.
Bees LD50 (contact)	> 40 µg / bee

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3) Consumption data not available.

As already stated above, Kasugamycin is a systemic fungicide and bactericide used at a very low dose @ 30-50g ai / ha.) on rice crop for the control of blast disease only. Occurrence of the blast disease on rice is limited to certain area in the rice growing states of the country. As per the information available, consumption data for the last three years is given as under:-

S.No.	Year	Consumption
1.	2003-04	120 KL
2.	2004-05	130 KL
3.	2005-06	145 KL

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Thank you


2)

Linuron

Meeting with Expert Group
New-Delhi

March 19, 2007

Dr. Geeta Dagan




MAKHTESHIM-AGAN INDUSTRIES LTD.

1

Overview

- Makhteshim-Agan: Overview
- Linuron – Overview of the product
- Worldwide Status of Linuron
- Makhteshim-Agan position
- Toxicity and Classification
- MRL and Consumer risk assessment
- Advantages to the market in India




MAKHTESHIM-AGAN INDUSTRIES

2

Makhteshim-Agan - Background

- A merger of Makhteshim (Est. 1952) and Agan (Est. 1945).
- Focus on: Herbicides, Insecticides and Fungicides.
- Non Agro activities: Antioxidants/vitamins, Optical brighteners, Basic chemicals and Aroma chemicals
- Market Cap: \$2.4 billion
- Ownership:

Koor Industries	34%
Public	66%




MAKHTESHIM-AGAN INDUSTRIES

3

Makhteshim-Agan Business Profile

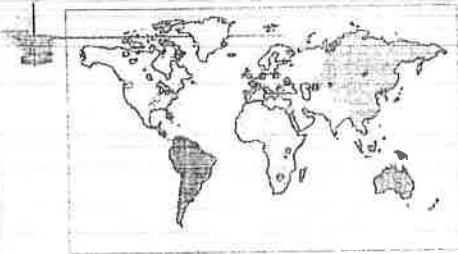
- World's leading manufacturer and distributor of generic agrochemical products
- Global presence
- Broad product portfolio
 - 70 Active ingredients, 500 formulations sold worldwide
 - 4000 Registrations in 120 countries
- State-of-the-art technological capabilities in organic synthesis and formulation



MAKHTESHIM-AGAN INDUSTRIES

4

Global Presence



- 38 subsidiaries in 24 countries
- Sales to over 100 countries worldwide
- Over 3000 employees worldwide



MAKHTESHIM-AGAN INDUSTRIES

5

Agrochemical Companies Ranking 2004

COMPANY	2004	2003	% CHANGE	Market Share 2004
1 Bayer	7,050	5,207	12.8%	22.6%
2 Syngenta	6,039	5,421	11.2%	19.6%
3 BASF	4,166	3,582	16.1%	13.6%
4 Dow	3,143	2,800	12.3%	10.2%
5 Monsanto	2,864	2,784	2.8%	9.3%
6 DuPont	2,210	2,018	9.5%	7.2%
7 FMC	1,854	1,735	10.0%	6.1%
8 SunKoma Chemical	1,170	859	36.2%	3.8%
9 Nufarm	791	604	31.8%	2.6%
11 Aryzta	704	660	10.0%	2.3%
13 Cheminova	492	371	31.5%	1.6%

Total Conventional Crop-Protection Market = \$ 33 billion

Source: Philip McDougall Agriculture (April 2005)



MAKHTESHIM-AGAN INDUSTRIES

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Makhteshim-Agan

- 2006 sales: \$ 1.8 B
- The largest generic agrochemical company in the world.

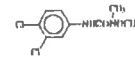


MAKHTESHIM-AGAN INDUSTRIES

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Linuron – Active ingredient

- Chemical name
- (IUPAC) 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea
- (CA) N'-(3,4-dichlorophenyl)-N-methoxy-N-methylurea
- CIPAC No. 76
- CAS No. 330-55-2
- FAO SPECIFICATION AGP: CP/83
- M.W. 248.1
- Structural formula



- First registered in USA in 1980



MAKHTESHIM-AGAN INDUSTRIES

8

Linuron – USES

- A selective herbicide for both pre- and post-emergence applications.
- Controls many species of broadleaf and grass weeds.
- **Crops:** corn, soybeans, sunflower, peas, beans, cotton, potatoes, carrots, asparagus, artichoke, celery, leek, fennel/anise, parsley, parsnips, sweet potatoes, onion, garlic, wheat, barley, and orchards (apple, pear, peach), almonds, vineyards, flowers, coffee tree, cacao tree, banana.
- **In India** registered for potatoes only.



MAKHTESHIM-AGAN INDUSTRIES

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List of weeds

Sensitive: *Amaranthus retroflexus* (AMARE); *Anagallis arvensis* (ANGAR); *Atriplex patula* (ATXPA); *Capsella speciosa* (CAPSS); *Chenopodium sp.* (CHESS); *Echinochloa crus-galli* (ECHCG); *Galinoga parviflora* (GASPA); *Lamium purpureum* (LAMPLU); *Matricaria chamomilla* (MATCH); *Myosotis arvensis* (MYGAR); *Papaver rhoeas* (PAPRH); *Polygonum* 2 (POLSS); *Senecio vulgaris* (SENVU); *Simons arvensis* (SINAR); *Sonchus speciosus* (SONSS); *Stellaria media* (STEME); *Thlaspi arvense* (THLAR); *Veronica* (VERSS)

Moderately sensitive: *Brassica napus* (BRSNM); *Echinochloa crus-galli* (ECHCG); *Matricaria chamomilla* (MATCH); *Poa annua* (POAAN); *Polygonum persicaria* (POLPE); *Viola arvensis* (VIAR)

Tolerant: *Alopecurus myosuroides* (ALOMY); *Cirsium arvense* (CIRAR); *Elytigia repens* (AGRE); *Galium aparine* (GALAP); *Polygonum convolvulus* (POLCO); *Triticum aestivum* (TRZAW)



MAKHTESHIM-AGAN INDUSTRIES

10

Makhteshim-Agan Position

- Agan has produced Linuron since 1976
- In Feb. 2003, Agan acquired the worldwide business of the product from Bayer CropScience
- Two brand names
 - Afalon and Linurex
- Agan is the owner of the basic
 - Registrations
 - Trade names
 - Patents
- Regulatory data (files, studies, summaries and assessments)



MAKHTESHIM-AGAN INDUSTRIES

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Linuron - Products

- Agan is the worldwide basic manufacturer of Linuron products
- Technical grade
- Formulations:
 - Linuron SC formulations: 450 g/L and 500 g/L
 - Linuron WP formulations: 475 g/kg and 500 g/kg
- Mixtures
 - Linuron + Trifluralin, Linuron + Chlorotoluron



MAKHTESHIM-AGAN INDUSTRIES

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Linuron - Worldwide registrations

- Agan: 133 registrations in 51 countries including:
USA, Canada, Most Western and Eastern Europe countries, Australia, New Zealand, South-Africa, Most Latin America countries, Africa, Asia
- Both Agan's original registrations and registrations transferred from Bayer
- In India transfer of registration is still ongoing



MAHESHIMA-AGAN INDUSTRIES

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Status in EU

- Agan - about 40 registrations in EU (technical grade and formulations)
- Latest evaluation of the product
- Agan was a member of the EU Task Force (April 1995) together with AgrEvo (Bayer) and I.Pi.Cl
- RMS: UK
- Official Annex I inclusion: 31 Dec. 2003
- Approval until 31.12.2013 in 27 EU countries



MAHESHIMA-AGAN INDUSTRIES

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Linuron - Toxicity

- **Acute Toxicity - technical grade**
- Acute oral LD₅₀ (rat) 4800 mg/kg
- Acute dermal LD₅₀ (rat) > 2000 mg/kgbw
- Acute Inhalation LC₅₀ (rat) > 4.1 mg/L
- Skin irritation (rabbit) - Non irritant
- Eye irritation (rabbit) - Mild irritant
- Skin sensitisation (guinea pig) - Non-sensitiser



MAHESHIMA-AGAN INDUSTRIES

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Acute Toxicity (Product)

- **Acute Toxicity -WP formulation**
- Acute oral LD₅₀ (rat) 5909 mg/kg
- Acute dermal LD₅₀ (rat) > 2000 mg/kgbw
- Acute Inhalation LC₅₀ (rat) > 5.47 mg/L
- Skin irritation (rabbit) - Non irritant
- Eye Irritation (rabbit) - irritating
- Skin sensitisation (guinea pig) - Non-sensitiser



MAHESHIMA-AGAN INDUSTRIES

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Long-term toxicity and carcinogenicity, Rats

Study	NOAEL	Dose	Reference
Rat, 2 years, oral (diet)	125 ppm	0, 25, 125, 625 ppm (35/sex/dose)	Hodges et al, 1998

Findings: Increased mortality at 6-15 months in all dose levels because of infection of the respiratory tract. Organ weight, urinalysis and hematological parameters within normal during the study. At 625 ppm: reduced body weight gain, haemotoxic effects during histological examination of the spleen and liver. Females: endometrial hyperplasia (5/12). Males: Benign Leydig cell adenoma in the testes.

Rat, study 1

- **Discussion:** Tumors developed in aged animals also in control and low dose
- Not adequately performed in several aspects
- The study was considered not acceptable in the PSD, EU reviews. Not evaluated in EPA.
- A 2nd study was necessary

Long-term toxicity and carcinogenicity, Rats (cont.)

Study 2	NOAEL	Dose	Reference
Rat, 2 years, oral (diet)	50 ppm (2.5 mg/kg/day)	0, 50, 125, 625 ppm (70/sex/dose)	Kaplan et al, 1980

Adverse effects: inhibition of body weight gain, hemolytic anemia with lowering of the erythrocyte count, hemosiderin deposits. Male: Increase in testis weight connected to increase in the incidence of benign adenomas of Leydig cell type at ≥125 ppm. Females: endometrial hyperplasia (25/67), indication of hepatotoxicity.

Rat, Study 2

Discussion:

- Leydig cell tumor is not considered relevant to human risk assessment. A thorough investigation was published in 1999. "Cook J.C. et al., Rodent Leydig Cell Tumorigenesis: A Review of the Physiology, Pathology, Mechanisms and relevance to Humans, Critical Reviews in Toxicology, 29(2) pp. 169-261 (1999)"

"In conclusion, the data suggests that nongenotoxic compounds that induce Leydig cell tumors in rats, most likely have low relevance to humans under most exposure conditions, because humans are quantitatively less sensitive than rats."

Discussion (cont.)

- Tumors were considered age related (was observed in controls and in the lower dose, within the biological range observed in aging male rats)
- As Linuron is not mutagenic, a non-genotoxic mechanism of tumorigenic effect was postulated.



Long-term Rats (cont.)

Study 3	NOAEL	Dose	Reference
Rat, 24-27 month, oral (diet)	25 ppm (1.25 mg/kg bw/day)	0, 25, 200, 1600 ppm (80/sex/dose)	Donaubauer et. al, 1982

In male: benign testicular interstitial cells tumors (Leydig cell) at 200 and 1600 ppm

In females: increase in ovarian tumors at 1600 ppm (5/58) and slightly at 200 ppm (2/58)



Rat, study 3

Discussion:

- The high dose was in excess of the Maximum Tolerated Dose (MTD) - not relevant
- Finding in females - not significantly different from control at the mid and low dose and also are age related effects
- Findings in males: Leydig cell tumors - not relevant to human
- Tumors are age related



Long-term toxicity and carcinogenicity, Mice

Study 4	NOAEL	Dose	Reference
Mice, 2 years, oral (diet)	150 ppm (23-35 M,F mg/kg bw/day)	0, 50, 150, 1500 ppm (80/sex/dose)	Rickard et al, 1982

At 1500: reduced BW gain and food consumption. No clinical symptoms during the clinical phase. Haemostasis in liver and spleen. Increased liver weight and changes in liver: Females: hepatocellular neoplasms (no metastases)

At 150 ppm: Liver findings not significantly different from control



Mice (cont.)

Discussion:

- The high dose was in excess of the Maximum Tolerated Dose (MTD) and caused chronic toxicity in the liver.
- Was performed for registration in Japan, request of a dose level producing marked signs of intoxication even mortality.
- The observed liver tumor occur spontaneously in some strains of mice and were found in the control group of this assay, too.
- Liver tumor in the mid and low dose were within the historical control range.



MAKHTESHIM-AGAN INDUSTRIES

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Carcinogenicity potential

Rats:

- Significant findings at high concentrations (>MTD) which caused toxicity and even mortality
- Tumors developed in aged animals also in controls
- Females: Not significantly different from control and considered age-related

- Males: Leydig cell tumors- not relevant to human

Mice:

- A significant increase in liver tumor incidence was found only at high concentrations (>MTD) which induced other signs of chronic toxicity in the liver
- At other doses: Findings not different from controls data



MAKHTESHIM-AGAN INDUSTRIES

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Mutagenicity potential

- After a review of a battery of studies of the three categories (gene mutations, chromosomal aberrations and DNA damage and repair) – Linuron was considered to be not mutagenic by both the US-EPA and the EU authorities



MAKHTESHIM-AGAN INDUSTRIES

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MRL and Dietary Exposure

- Tolerances available from USA, EU and other authorities in many agricultural commodities
- Usually residues are very low (at LOD)
- MRL in potato: 0.05 mg/kg (European Union); 1 mg/kg in USA



MAKHTESHIM-AGAN INDUSTRIES

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Consumer Risk Assessment

- PSD and German models
- Most sensitive group is infants
- Chronic dietary exposure:
 - Theoretical Maximum Daily Intake (TMDI) is 7.3% of ADI
- Acute dietary exposure:
 - Acute dietary intake for Infants is 20.5% of ARfD



MAKHTESHIM-AGAN INDUSTRIES

29

Reviews in USA and classification

- First registered in 1960 and still sold
- A special review between 1984-1988 on the carcinogenicity potential.
 - Conclusion of the review: should not be regulated as a carcinogen – reduced cancer classification
- Review (1995) – RED was issued
- Classification **remained** as Group C carcinogen (a possible human carcinogen for which there is limited animal evidence)



MAKHTESHIM-AGAN INDUSTRIES

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Reviews in Europe

- UK-PSD review on 1996
- EU-review between 1995-2003
 - Conclusions: Not carcinogenic
 - Classification: Cat. III, R40 – Limited evidence of a carcinogenic effect (same as many herbicides especially urea herbicides)



MAKHTESHIM-AGAN INDUSTRIES

31

Status in former USSR

- No urea herbicides were registered in former USSR
- AgrEvo decided not to register in USSR based on economic reasons
- Agan re-evaluated the commercial potential. We will start registrations in Russia and Ukraine (only countries with economic potential)



MAKHTESHIM-AGAN INDUSTRIES

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Status in Sweden

- Was banned in 1995 probably as a result of comparative assessment (less toxic product was available for the same area of use)
- EU review between 1995-2003 resulted in a positive decision
- Agan can re-register the product based on the new risk assessments from the EU review
- The Scandinavian market is very small – Development is not justifiable economically

MAKHTEB/IB-AGAN INDUSTRIES 33

Status in India

- Registration received in Aug. 1998 by Bayer (Technical and WP formulation)
- Bayer sold the product in India between 1999 – 2001 for use in potatoes.
- Quantities sold: 2.5 to 6 MT formulation yearly. in the states of Uttar Pradesh, Gujarat, West Bengal and Tamil Nadu

MAKHTEB/IB-AGAN INDUSTRIES 34

Status in India (cont.)

- Agan acquired the product on Feb. 2003
- Worldwide registration were transferred from Bayer to Agan after the purchase
- Agan plans to develop the product in potatoes and possibly in other crops when transfer of registration is completed

MAKHTEB/IB-AGAN INDUSTRIES 35

Status in India (Cont.)

Advantages:

- Resistance not developed yet in India
- No need of pre-plant incorporation
- Can be used in many crops of various families
- A broad spectrum of weeds

MAKHTEB/IB-AGAN INDUSTRIES 36

Bayer Divested Linuron to Makhteshim-Agan

INDIA MARKET SITUATION

- Product introduced in the market in 1999
- Linuron 50%WP sold in Potato markets till 2001
- Bayer divested Linuron worldwide to Makhteshim-Agan
- Makhteshim-Agan waiting for legal formalities of divestment to be completed worldwide
- Once registration is transferred, Makhteshim-Agan has ambitious plans to market Linuron in India
- Label expansion in various crops planned



MAKHTESHIM-AGAN INDUSTRIES

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Consumption data available in India

Sales figures from Bayer India:

Year - MT Sold

- 1999 - 2.5 MT
- 2000 - 6.0 MT
- 2001 - 3.3 MT

Marketed in all major Potato growing states

- West Bengal
- Uttar Pradesh
- Gujarat
- Tamil Nadu



MAKHTESHIM-AGAN INDUSTRIES

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Consumption data available (India)

Our field experience in India

- No resistance problem reported so far in India
- Great scope for extending the application to many crops
- Linuron is relatively a better broad leaved (dicot) weed killer in Pea & Potato (registered crops) than Fluochloralin, Pendimethlin
- Pre Planting soil Incorporation not required in the case of Linuron application which is cumbersome, costly and is a MUST for volatile products like Fluochloralin
- Linuron relatively provides better persistence (more number of weed free situation)



MAKHTESHIM-AGAN INDUSTRIES

39

Salient features of Linuron

- Stable in soil with wider range of pH 5, 7 and 9
- Water solubility is less (81mg/l), hence no leaching expected to contaminate water
- Pre Planting soil Incorporation not required
- Linuron relatively provides better persistence, so prolonged control of weeds for better crop growth



MAKHTESHIM-AGAN INDUSTRIES

40

Summary

- Agan's Linuron is approved and sold in many countries worldwide
- Agan is the main data holder of Linuron
- Carcinogenic effect tested in animal
- Low risk to consumers by consumption of edible parts of plant or animal products
- Beneficial to the Indian market



MAHESHWARI-ADANI INDUSTRIES

41

Thank you



MAHESHWARI-ADANI INDUSTRIES

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**REVIEW OF MEPIQUAT CHLORIDE BY
EXPERT COMMITTEE ON 14TH DECEMBER 2006**

PRESENTATION BY :

**DR. K.N.SINGH
GHARDA CHEMICALS LTD.**

MEPIQUAT CHLORIDE

- Is a systemic plant growth regulator used to regulate vegetative growth to enhance reproductive potential in crops / plants viz. cotton, potato and grapes.
 - Used in cereals to shorten the stems to prevent lodging
 - Belongs to piperidine family. Technical is highly hygroscopic, therefore, water based technical concentrate and aqueous formulations are registered globally.
 - Registered during 2003 u/s 9(3) by Gharda Chemicals as Mepiquat Chloride 50% TK and 5% AS for use on Potato @ 62.5 -- 75 gm a.i. ha⁻¹
- CONCERN:**
- > The Product Is Severely Restricted in Belize. Use Allowed As a Defoliator for Only in Cotton.
 - > The Product Is Banned in Norway Because of Low Degradability in Water.
 - > Consumption Data For Mepiquat Chloride.

CONCERN

The product is severely restricted in Belize. Use allowed as a defoliator for only in cotton.

• Mepiquat chloride is registered globally.

• It is recommended on cotton, potato, grapes and cereals.

Country	Registered Strength
Australia	5.0% AS
Greece	5.0% SL
India	50% TK and 5.0% AS
Indonesia	5.0% AS
Ireland	5.0% AS
Morocco	40.0% TK
Romania	50% TK
Spain	56.45% TK and 5% AS
U.S.A	4.2 to 23.5% EC

CONCERN

The product is banned in Norway because of low degradability in water

- Estimated average concentration of mepiquat chloride in surface and ground water are 1.99 ppb and 0.008 ppb respectively, whereas, drinking water level of concern (DWLOC) are as follows :

US population	: 21,000 ppm
Females (13+ year old)	: 1,800 ppm
Children (1-6 year old)	: 570 ppm

-The estimated average concentration of mepiquat chloride in surface and ground water are significantly less than level of concern in drinking water (DWLOC).

.....Ref : EPA Federal Register Document on mepiquat chloride,
pesticide tolerances for emergency exemptions. Volume
63, number 188, page nos. 6-8.

CONCERN
Consumption Data For Mepiquat Chloride

Year	A.I.	Formulation (5% AS)
2004-05	2.4 MT	48.5 KL
2005-06	1.0 MT	20.0 KL



PROFITE
Generali

Dr. Rajeev Pant
Senior Manager Regulatory Affairs
Bayer Crop Science India



Review Meeting/ Presentation on 14th Dec. 06/Presenter : Rajeev Pant • Slide 1

General Overview

Registration Status in India

- Product is registered and being sold in India since 2002.

Formulation	Approved uses	Target Diseases
Propineb 70 WP (Antracol)	Apple	Scab
	Pomegranate	Leaf & Fruit spots
	Potato	Early & Late Blight
	Chilli	Die back
	Tomato	Buck eye rot
	Grapes	Downy Mildew

- Data generation for approval of label claim on additional crops viz. Rice, Cotton, Onion, Tea and Black gram are in progress.

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Rajeev Pant • Slide 4

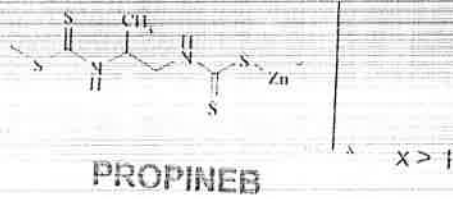
Concerns raised by Dr. K. S. Narayana

The following concerns raised would be addressed by our experts :

- (I.) "Propineb has a goitrogenic effect. Following oral administration, high tissue concentration and enlargement of the thyroid and pituitary gland occurs. Significant thyroid enlargement occurred in males at dietary levels of 100 ppm and above."
- (II.) "Product is banned in Sweden. Reason not available."
- (III.) "Consumption data not available."

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Rajeev Pant • Slide 5

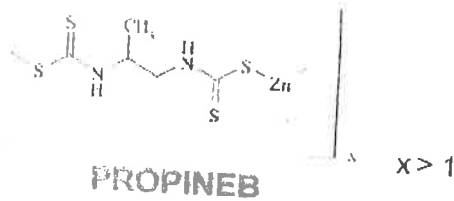
General Overview



- Polymeric zinc-compound of propylene dithio-carbamic acid
- Broad-spectrum contact fungicide used for controlling various diseases in a wide range of crops (cereals, fruits, vegetables, pulses, oil seeds etc.)
- Multi-site mode of action which prevents the development of resistance

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Rajeev Pant, Slide 2

General Overview



- Used in spray formulations
- Widely used as an ideal mixing partner in combination fungicides especially for control of oomycetes diseases
- Registered in over 70 countries
(e.g. Australia, France, United Kingdom, Japan)

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Rajeev Pant, Slide 3

Concerns raised by the Review Committee

The following concerns raised would be addressed by our experts :

- (I.) "Propinob has a goitrogenic effect. Following oral administration, high tissue concentration and enlargement of the thyroid and pituitary gland occurs. Significant thyroid enlargement occurred in males at dietary levels of 100 ppm and above."
- (II.) "Product is banned in Sweden. Reason not available."
- (III.) "Consumption data not available."



Division of Crop Science

(1) Propylthiouracil has a goitrogenic effect. Following oral administration, high tissue concentration in, and enlargement of the thyroid and pituitary gland occur. Significant thyroid enlargement occurred in rats fed diets of 100 ppm and above.

Kerstin Hartmann
Global Toxicology Expert, BCS Germany

Reference March 1977

"Propineb has a goitrogenic effect. Following oral administration, high tissue concentration in, and enlargement of the thyroid and pituitary gland occurs. These effects are reversible."

Pituitary gland enlargement only mentioned in this report.

But: not observed in the studies conducted so far
Therefore never mentioned in subsequent JMPR reports

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Kerstin Hartmann • Slide 7

○ Thyroid effects occurred at 100 ppm and above

(1st study: 5-10-25-50-100 ppm, 2nd study: 1-10-100-1000-2000-8000 ppm)

MTD exceeded at 2000 ppm (partially lethal dose)

○ Decreased protein-bound iodine at 100 ppm

○ Increased thyroid weight

○ in males at 100 ppm and above

○ in females at 1000 ppm

○ Increased incidence of thyroid hyperplasia and adenoma at 1000 ppm and above

○ But no thyroid effects occurred in chronic mouse and dog studies

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Kerstin Hartmann • Slide 8

Mechanistic rat studies on thyroid effects

○ Reversibility of thyroid enlargement

- Thyroid enlargement is reversible after 8 weeks recovery period following 6 month treatment of 500 ppm Propineb.

○ Thyroid NOAEL

- Overall NOAEL: 10 ppm (0.74 mg/kg bw/day)
 - ⇒ JMPR, EU: ADI: 0.007 mg/kg bw/day

○ The rat is an extremely sensitive species to thyroid effects compared to human (and dogs and mice)

- Circulating thyroid hormones are bound to protein (Thyroxin Binding Globulin) and therefore not biologically active
 - >99% in humans
- Lack of Thyroxin Binding Globulin in rat
 - Low storage capacity of thyroid hormones
- Thyroid neoplasia is limited to rat, based on resulting long lasting overstimulation

○ Monitoring of 77 workers at Bayer Germany, 3 of them over 30 years, revealed no evidence of goitrogenic effect in humans

Human risk assessment for Propineb

- Established ADI of 0.007 mg/kg bw/day is safe
 - ADI is based on the NOAEL of the "unrealistically sensitive" rat:
 - ✦ Rat: NOAEL: 0.74 mg/kg bw/day
 - ✦ Dog: NOAEL: 25 mg/kg bw/day
 - ✦ Mouse: NOAEL: 106 mg/kg bw/day
 - ✦ Safety factor of 100 (default)
- Margin of safety (MOS) between ADI and thyroid weight increase in rat: approx. **1000**
- Since humans are less sensitive than rats the respective MOS for humans is even greater

Review Meeting/ Presentation on 14th Dec. 08/Presenter: Kerstin Hartmann • Slide 11

- Thyroid effects occurred only in the rat
 - ✦ This thyroid enlargement is reversible
 - ✦ Mechanism of thyroid suppression is clearly understood
 - ✦ Rat thyroid neoplasia not relevant to human
- ADI is safe since based on the NOAEL of the "unrealistically sensitive" rat
- Large MOS for human between ADI and thyroid weight increase in rat

Review Meeting/ Presentation on 14th Dec. 08/Presenter: Kerstin Hartmann • Slide 12



Bayer CropScience

(ii) "The product is banned in Sweden. Reason not available."

Dr. Raimund Grau
Global Product Safety Manager

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 13

Background to the Propineb registration in Sweden

- UN List 2002 - Remarks: voluntarily withdrawn
- Reasons:
 - In 1990, Bayer evaluated the Swedish market and came to the conclusion, to sell only Tolyfluanid (Euparen M) as multi-site fungicide due to economic reasons.
 - For that reason Bayer stopped the Propineb sales in 1992 and consequentially the registration of Propineb was voluntarily withdrawn from the Swedish market by the Swedish Bayer Subsidiary (Bayer AB).
- Any interpretation in direction of a compound ban is misleading.

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Reinhard Grau - Slide 14

- Propineb was assessed by the EU Member States and the European Food Safety Authority and in 2004 Propineb was included into Annex I (positive list).
- The Annex I listing is mandatory for all EU Member States and for that reason all Annex I listed actives can be registered in all EU Member States (includes Sweden).

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Reinhard Grau - Slide 15



Healthier CropScience

(III) Consumption data not available

Review Meeting/ Presentation on 14th Dec. 06/Presenter : Raimund Grau • Slide 16

- Propineb 70% WP (Antracol®) is the only formulation registered in India.
- About 581 MT of Propineb technical was consumed in India in year 2005 for making about 681 MT of Propineb 70% WP (Antracol®).

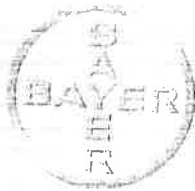
Review Meeting/ Presentation on 14th Dec. 06/Presenter : Raimund Grau • Slide 17



Bayer CropScience

Thank you very much for your kind
attention



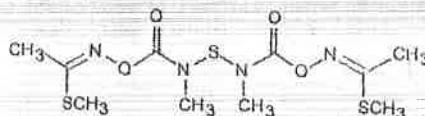


Bayer CropScience

Thiodicarb
General Overview

Mr. Rajesh Dhawan
Senior Manager Registration
Bayer CropScience India

General Overview



THIODIGARB (LARVIN®)

Chemical name (IUPAC and CA nomenclature)

IUPAC : 3,7,9,13-tetramethyl-5,11-dioxa-2,β,14-trithia-4,7,9,12-tetra-azapentadeca-3,12-diene-6,10-dione

CAS : dimethyl N,N'- [thiobis [(methylimino) carbonyloxy]] - bis(ethanimidothioate)

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Rajesh Dhawan • Slide 2

General Overview

Thiodigarb

- belongs to the carbamate group
- acts as a cholinesterase inhibitor with slow initial effect
- exhibits combined ovicide, larvicide, adulticide and residual activity
- primarily as an ingestion or stomach toxicant with some complementary contact action

Commercial products

- Larvin™ is used as a foliar spray application.
- Semevin™ and Future™ are effective as seed treatment
- Skipper™ is also used as a molluscicide.

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Rajesh Dhawan • Slide 3

General Overview

Thiodicarb

- is registered and sold worldwide in more than 40 countries since last 20 years
- is non-systemic, exhibits minimal contact activity, combined with a narrow pest spectrum makes Larvin ideally suited to integrated pest management
- is used in key segments worldwide:
 - cotton, corn, soybean, wheat, fruits, vegetables and ornamentals
 - in Crop Protection (Larvin™ 35SC, 37.5SC, 80WG and 75WP)
 - in Seed Treatment (Future™ 30FS, Samevin™ 35FS and Krisol™ 80SG)
- and in India:
 - cotton, cabbage and brinjal

Review Meeting/ Presentation on 14th Dec. 08/Presenter: Rajesh Dhawan • Slide 4

Registration Status in India

- Product is registered and being sold in India since 1998.

Formulation	Approved uses	Target Insect Pests
Thiodicarb 75 WP (Larvin 75 WP)	Cotton	Bollworms
	Cabbage	DBM
	Brinjal	Shoot & Fruit Borer

- Data generation for approval of label claim on additional crop viz. Blackgram is in progress.

Review Meeting/ Presentation on 14th Dec. 08/Presenter: Rajesh Dhawan • Slide 5

Consumption of Thiodicarb

- Thiodicarb 75% WP (Larvin 7 formulation of Thiodicarb registered in India.
- About 253 MT of Thiodicarb technical was consumed in India in the year 2005 which was used for making about 320 MT of Thiodicarb 75% WP formulation.

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Rajesh Dhawan • Slide 6

Concern raised by the Review Committee

The following concern raised would be addressed by our experts :

- Severely restricted for use only in Cotton in Belize due to high toxicity.

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Rajesh Dhawan • Slide 7



Bayer CropScience

Severely restricted for use only in Cotton
in Belgium due to high toxicity

Dr. Raimund Grau
Global Product Safety Manager, BCS Germany

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 8

History of the severe restriction in cotton in Belize

In 1990, Belize has restricted use of Larvin® in cotton due to its "high toxicity", most probably without a proper risk evaluation.

This restriction has been submitted to the PIC (Prior Informed Consent) Secretariat,

however this notification does not meet the requirements of the PIC Convention and will therefore not be considered (see PIC Circular X - 12/1999).



Interim Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade



PIC CIRCULAR X - December 1999

Common Name: Thiodicarb

Chemical Name: Ethionamideacetic acid, N,N'-[bis[2-(methylthio)ethyl]carbonyl]bis[2-(methylthio)ethyl] ester CAS: 50660-26-0

Severely restricted. For use only in cotton. High toxicity.

Notification Date: 12/23/1999

Notification does not meet information requirements of Annex I of the Convention

Review Meeting/ Presentation on 14th Dec. 00/Presenter: Raimund Grau - Slide 9

Fast track to restriction in cotton in Belize

Bayer CropScience withdrew voluntarily from the market in May 2003 due to commercial reasons

Table 2.1:

Table 2.1: List of Pesticides Withdrawn from the Market in Belize

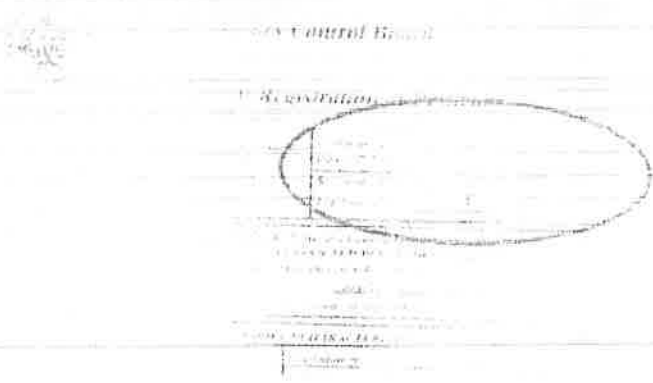
Product Name	Registration No.	Withdrawal Date
1. Actin 70 EC	0068-1	05/2003
2. Alatta 80 WG	0042-2	05/2003
3. Alatta 80 WP	0042-1	05/2003
4. Asulox 40 SL	0004-1	05/2003
5. Caracox 5,05 RB	0292-1	05/2003
6. Conidor 35 SC	0247-3	05/2003
7. Cupravit Azin 35 WC	0024-2	05/2003
8. Dipelex 05 SP	0051-2	05/2003
9. Dipelex 10 GR	0238-1	05/2003
10. Ethrol 48 SL	0238-1	05/2003
11. Ficam 20 WP	0009-1	05/2003
12. Folidol 25 CG	0121-3	05/2003
13. Folidol M 2 DP	0121-2	05/2003
14. Larvin 37.5 SC	0229-2	05/2003
15. Lehgvold 60 EC	3103-1	05/2003
16. Matesystox 20 EC	3005-2	05/2003
17. Matesystox 50 SL	0088-1	05/2003
18. Nemasur 40 EC	0108-1	05/2003
19. Tamaron 40 SL	0113-1	05/2003
20. Tokuthion 60 EC	0270-1	05/2003
21. Vectra BN 20 EC	0283-1	05/2003
22. Volaton 5 DP	0080-1	05/2003
23. Volaton 5 GR	0080-3	05/2003
24. Volaton 50 EC	0060-4	05/2003

1. Actin 70 EC 0068-1
2. Alatta 80 WG 0042-2
3. Alatta 80 WP 0042-1
4. Asulox 40 SL 0004-1
5. Caracox 5,05 RB 0292-1
6. Conidor 35 SC 0247-3
7. Cupravit Azin 35 WC 0024-2
8. Dipelex 05 SP 0051-2
9. Dipelex 10 GR 0238-1
10. Ethrol 48 SL 0238-1
11. Ficam 20 WP 0009-1
12. Folidol 25 CG 0121-3
13. Folidol M 2 DP 0121-2
14. Larvin 37.5 SC 0229-2
15. Lehgvold 60 EC 3103-1
16. Matesystox 20 EC 3005-2
17. Matesystox 50 SL 0088-1
18. Nemasur 40 EC 0108-1
19. Tamaron 40 SL 0113-1
20. Tokuthion 60 EC 0270-1
21. Vectra BN 20 EC 0283-1
22. Volaton 5 DP 0080-1
23. Volaton 5 GR 0080-3
24. Volaton 50 EC 0060-4

Review Meeting/ Presentation on 14th Dec. 00/Presenter: Raimund Grau - Slide 10

History of the severe restriction in cotton in Belize

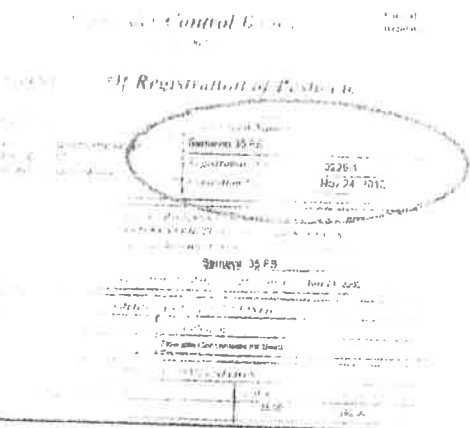
- Bayer CropScience withdrew voluntarily from the market in May 2003 due to commercial reasons
- although registration for Larvin 37.5 SC was valid until November 2005



Review Meeting/ Presentation on 14th Dec. 03/ Presenter: Raimund Grau • Slide 11

Thiodicarb in Belize

- Thiodicarb is registered as Semevin 35 FS (350 g/l) as Seed Treatment for:
Cotton, Soybean, Bean, Sesame, Sorghum grain, Wheat and Maize (corn)



Review Meeting/ I

Summary

- The restriction on cotton in Belize
 - is an isolated case
 - based on an improper risk assessment
 - reason not sufficient to PIC-list Thiodicarb
- In Belize the product is registered in 2005 for use as a seed treatment on cotton, soya beans, corn etc.
 - Registration is up to 2010
- The product is registered and sold in more than 40 countries
 - including key cotton growing countries namely USA, Brazil, Australia, Pakistan, China etc.

Review Meeting/ Presentation on 14th Dec. 06/Presenter: Raimund Grau • Slide 13



Bayer CropScience

Thank you very much for your kind
attention

TRICHLORFON

By:

United Phosphorus Ltd.

Presentation by:

Dr. Ajit Kumar

"Review of various pesticides which are banned in other countries but are being used in India - Trichlorfon" : Presentation made to Review Committee on 20th Feb, 2007 at Krishi Anusandhan Bhawan-II, I.A.R.I., Pusa, New Delhi.

Trichlorfon : The Concerns

Trichlorfon : The Concerns

1. **Banned in Kuwait due to health and environmental reasons. No remaining uses are allowed.**
2. **Restricted in Indonesia. Reason for restriction not available. Being permitted on its use for both commodities. Still allowed for use until 1996 only for recommended target crop as well as target pest. Use under the provision of supervision.**

(Reference: Consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by the Govts., VII issue, Chemicals, United Nations, New York, 2002)

Trichlorfon : Banned in Kuwait

Trichlorfon : Banned in Kuwait

- Economic crops are oilpalms and dates.
- Trichlorfon is not approved for use in oilpalms and dates in India.
- Hence, scope for use of Trichlorfon in Kuwait is limited.
- Also, Indian agro-climatic conditions cannot be compared with that of Kuwait.

The ban in Kuwait is not truly relevant in Indian Context.

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Trichlorfon : Restricted in Indonesia

6

Trichlorfon : Restricted in Indonesia

- Trichlorfon 95% SP is still used against the recommended target pest.
- A total of 28 pesticides were banned for use on rice by presidential decree in 1986 including Trichlorfon.

(Sources: Decree of the Indonesian Minister of Agriculture, Number 473/KPTS/TP.270/6/96; PAN Asia and the Pacific, "Call for a Worldwide Ban on Endosulfan," Press Release, June 16, 1996.)

*Contd...*⁷

Trichlorfon : Restricted in Indonesia

The list of products banned by the Decree of the Indonesian Minister of Agriculture

- | | |
|------------------------|------------------|
| • Acephate | • Isazophos |
| • Azinphos methyl | • Malathion |
| • Carbaryl | • Mephosfolan |
| • Carbophenothion | • Methomyl |
| • Chlorpyrifos | • Methamidaphos |
| • Cartap hydrochloride | • Monocrotophos |
| • Diazinon | • Ometheate |
| • Dichlorvos | • Piridafenthion |
| • Endosulfan | • Phenthoate |
| • Etrimfos | • Phosphamidon |
| • Fenitrothion | • Quinalphos |
| • Fenthion | • Cyanofenphos |
| • Fonofos | • Triazophos |

⁸

Trichlorfon : Worldwide Registration Status

Trichlorfon : Worldwide Registration Status

Countries where Use of Trichlorfon is approved

1.	Algeria	11.	Ecuador
2.	Argentina	12.	Ethiopia
3.	Australia	13.	India
4.	Bangladesh	14.	Iran
5.	Brazil	15.	Italy
6.	Canada	16.	Japan
7.	Colombia	17.	Jordan
8.	Costa Rica	18.	Kenya
9.	Croatia	19.	Macedonia
10.	Dominican Republic	20.	Malaysia

¹⁰
Contd...

Contd...

Trichlorfon : Worldwide Registration Status

Countries where Use of Trichlorfon is approved

21.	Mauritius	32.	Singapore
22.	Mexico	33.	South Africa
23.	Morocco	34.	Spain
24.	Mozambique	35.	Sri Lanka
25.	Namibia	36.	Thailand
26.	Pakistan	37.	Turkey
27.	Paraguay	38.	U.S.A.
28.	Peru	39.	Uruguay
29.	Philippines	40.	Venezuela
30.	Portugal	41.	Zambia
31.	Saudi-Arabia	42.	Zimbabwe

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**Trichlorfon :
Global Crop/Pest Approvals**

12

Trichlorfon : Global Crop/Pest Approvals

CROP	PEST
Cereal crops	Armyworms, Cutworm, common armyworm, southern armyworm (barley grub)
Legumes	Armyworms, common armyworm, southern armyworm (barley grub)
Maize	Armyworms, Cutworm
Pastures	Cutworm, Webworm, Armyworms, common armyworm, southern armyworm (barley grub)
Safflower	Cutworm, Rutherglen bug, grey cluster bug
Sorghum	Cutworm, sorghum head caterpillar
Soybeans	Green vegetable bug
Sugar cane	Armyworms
Sunflower	Armyworm, southern armyworm (barley grub), Cutworm
Tobacco	Green vegetable bug, Cutworm

Trichlorfon : Registration in India

Trichlorfon : Registration in India

Trichlorfon Registrations in India

- ***Trichlorfon Technical***
- ***Trichlorfon 50% EC***
- ***Trichlorfon 5% GR***
- ***Trichlorfon 5% DP***

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**Trichlorfon :
Crop/Pest Approvals In India**

16

<i>Trichlorfon : Crop/Pest Approval in India</i>			
Trichlorfon 50 EC			
No.	Crop	Pest	Dose g a.i./ha
1.	Wheat	Army worm	750
		Cut worm	750
2.	Bengal gram	Pod borer	400
3.	Ground nut	Red hairy caterpillar	500
4.	Sesamum	Bihar hairy caterpillar	500
5.	Brinjal	Fruit borer	500
6.	Cabbage	Diamond back moth	500

Contd...

<i>Trichlorfon : Crop/Pest Approval in India</i>			
Trichlorfon 50 EC			
No.	Crop	Pest	Dose g a.i./ha
6.	Cabbage	Tobacco caterpillar	750
7.	Cauliflower	Diamond back moth	500
		Tobacco caterpillar	750
8.	Cucurbits	Red Pumpkin beetle	500
9.	Tomato	Fruit borer	500
10.	Coffee	Hairy caterpillar	1500
11.	Tobacco	Capsule borer	1000
		Leaf eating caterpillar	1000
		Stem borer	1000

Contd... *Trichlorfon : Crop/Pest Approval in India*

Trichlorfon 5 G

No.	Crop	Pest	Dose g a.i./ha
1.	Maize	Stem borer	750
2.	Sorghum	Stem borer	750

Trichlorfon 5 DP

No.	Crop	Pest	Dose g a.i./ha
1.	Red gram	Pod borer	1000
2.	Castor	Semi looper	1000
3.	Ground nut	Pod borer	2000

Contd... *Trichlorfon : Crop/Pest Approval in India*

Label claim is deleted in the following crops :

1. Red gram
2. Bengal gram
3. Coffee
4. Tobacco

Reference : Gazette Notification- Draft No. 12, 2005; GSR No. 1292, Ministry of Agriculture and Co-operation.

Trichlorfon : Toxicological Profile

21

Trichlorfon : Toxicological Profile

- Acute oral toxicity (rat) : 250 mg/kg.
- Acute dermal toxicity (rat) : >5,000 mg/kg.
- Inhalation (4 h) (rat) : >2.3 mg/l air
- Skin irritation (rabbit) : Not irritant
- Eye irritation (rabbit) : Not irritant
- Mutagenicity : Non-mutagenic
- Carcinogenicity : Non-carcinogenic
- NOEL : Rat 100 mg/kg diet
Mice 300mg/kg diet
Dog 50 mg/kg diet
- ADI : 0.02 mg/kg b.w.
- Toxicity Class WHO (a.i.) : II

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Source : Pesticide Manual, 13th Edition/Bayer

Trichlorfon : Environmental Fate

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Trichlorfon : Environmental fate

- **In animals:** Trichlorfon is rapidly absorbed and metabolised. Excretion by urine is completed within 6 hours.
- **In Plants:** Trichlorfon is rapidly hydrolysed.
- **Soil/Environment:** Rapidly metabolised to CO₂. Hydrolysis and aerobic metabolism are the main routes of dissipation in soil and water.

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Trichlorfon : Conclusion

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Trichlorfon : Conclusion

- Trichlorfon is registered and used in more than 40 countries including the U.S.A. and Japan.
- No adverse effect reported either on efficacy or toxicity, despite of its use for over 3 decades.
- Restriction/ban in Indonesia & Kuwait is inappropriate to relate its ban in India.

In light of the above facts, we request for continued use of Trichlorfon in India.

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Thank You

for Your Valuable Time and Patient Hearing