OPERATION OF THE PRIOR INFORMED
CONSENT PROCEDURE FOR BANNED
OR SEVERELY RESTRICTED CHEMICALS
IN INTERNATIONAL TRADE

DECISION GUIDANCE DOCUMENTS

Dinoseb and its salts and esters

JOINT FAO/UNEP PROGRAMME
FOR THE OPERATION OF
PRIOR INFORMED CONSENT

United Nations Environment Programme
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ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

(n.b.: chemical elements and pesticides are not included in this list)

ADI	acceptable daily intake
ai	active ingredient
b.p.	boiling point
bw	body weight
^{o} C	degree Celsius (centigrade)
CCPR	CODEX Committee on Pesticide Residues
DNA	Designated National Authority
EC	emulsion concentrate
EEC	European Economic Community
EPA	U.S. Environmental Protection Agency
ERL	extraneous residue limit
FAO	Food and Agriculture Organization of the United Nations
g	ram microgram good agricultural practice guideline level
µg	microgram
GAP	good agricultural practice
GL	guideline level
ha	hectare
HEOD	
IARC	International Agency for Research on Cancer
i.m.	intramuscular
i.p.	intraperitoneal
IPCS	International Programme on Chemical Safety
IRPTC	International Register of Potentially Toxic Chemicals
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 103) kilogram
kg	kilogram
l	litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, median
m	metre
mg	milligram
ml	millilitre
m.p.	melting point

MRL	Maximum Residue Limit. (For difference between draft MRLs and Codex MRLs, see the introduction Annex I.)
MTD	maximum tolerated dose
ng	nanogram
NOEL	no-observed-effect level
NOAEL	no-observed-adverse-effect level
NS	Not Stated
OP	organophosphorus pesticide
PHI	pre-harvest interval
ppm	parts per million (Used only in reference to concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or are used).
sp gr	specific gravity
STEL	Short Term Exposure Limit
TADI	Temporary Acceptable Daily Intake
TLV	Threshold Limit Value
TMDI	Theoretical maximum daily intake
TMRL	Temporary Maximum Residue Limit
TWA	Time Weighted Average
UNEP	United Nations Environment Programme
WHO	World Health Organization
WP	wettable powder
wt	weight
<	less than
<<	much less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

DINOSEB AND DINOSEB SALTS

PRIOR INFORMED CONSENT
DECISION GUIDANCE DOCUMENT

1. IDENTIFICATION

1.1 Common Name: Dinoseb, DNPB, dinitro (WSSA, BSI, ISO), dinosebe (France)/Dinoseb-acetate (BSI, ISO)

1.2 Chemical Type: Dinitrophenol

1.3 Use: Pesticide, fungicide, herbicide, desiccant, insecticide, dormant fruit spray

1.4 Chemical Name: Dinoseb: 2-(sec-butyl)-4, 6-dinitrophenol/ Dinoseb Acetate: 0-acetyl-2-sec -butyl-4, 6-dinitrophenol

1.5 CAS No: 88-85-7

1.6 Trade Names/Synonyms: Basanite (BASF), Caldon, Chemox, Chemsect DNBP Nitro, Dinitro-3, Dinitro-General, Dynamyte (Drexal Chem.), Elgetol 318, Gebutox, Hel-fire (Helena), Kiloseb, Nitropone C, Premerge 3, Silnox General, (FMC), Subitex, Unicrop DNCP, Vertac Dinitro Weed Killer 5, Vertac General Weed Killer, Vertac Selective Weed Killer, dnpb, dinitro, dinosebe/Hoe 002904, Ivosit (Hoechst AG) Phenotan, aretit.

1.7 Mode of Action: Contact herbicide

1.8 Formulation Types: EC aqueous and oil solutions/EC50%, WP40

1.9 Basic Producers: Drexel Chemical (US), Hoechst AG (FRG), A.H. Marks & Co. (UK), Tifa Ltd. (UK), Uniroyal Chemical Co. (US), Universal Crop Protection (UK), Vertac Chemical Corp. (US)

2. SUMMARY OF CONTROL ACTIONS

2.1 General: Dinoseb has been banned in at least 10 countries with no uses being retained. Actions reported by governments are summarized in Annex 1.

2.2 Research for Control Action: Dinoseb and its acetate and their salts have been banned because they have been found in animal studies to result in high risks of birth defects, male sterility, high acute toxicity. Particularly at risk are applicators and other handlers of the pesticide. Countries may wish to review the use patterns and the exposed populations, especially as females are exposed.

2.3 Uses banned: Countries taking action have banned dinoseb for all uses.

2.4 Uses Reported to be Continued in Effect: No use has been reported as continuing in effect by those countries taking control actions.

2.5 Alternatives: No alternatives were suggested by those countries reporting control actions.

2.6 Contacts for Further Information: FAO/UNEP Joint Data Base, IRPTC, Geneva: designated national authorities in countries taking control actions listed in Annex 1.

3. SUMMARY OF FURTHER INFORMATION ON DINOSEB

3.1 Chemical and Physical Properties: Dark-brown solid or viscous liquid, melting point 30-40°C; soluble in organic solvents such as toluene, petroleum oil, ether, ethyl alcohol, ethanol, n-heptane, slightly soluble in water and miscible in ethyl ether and xylene. Technical dinoseb contains at least 90% active ingredient.

3.2 Toxicological Characteristics:

3.2.1 Acute Toxicity: a.i, Oral LD_{50} (rats) 40-60 mg/kg; dermal LD_{50}, 75 mg/kg

WHO Classification: a.i. Class Ib - Highly Hazardous

Formulations: Most liquid formulations are also in WHO Class Ib; WP formulations containing less than 95% a.i. are in Class 2.

3.2.2 Short-Term Toxicity: Induces birth defects in both rabbit and rat by oral exposure of 10 mg/kg/day during gestation; causes adverse male reproduction effects in the rat and mouse including decreased sperm counts (with partial or no recovery) and abnormal sperm cell morphology in rats and testicular atrophy in mice. Evidence strongly suggests that dinoseb is a potential human developmental toxicant to unborn children and a potential cause of human male reproductive disorders, such as decreased fertility or sterility. NOEL is 3 mg/kg/day for developmental effects and 10 mg/kg/day for maternal toxicity.

3.2.3 Chronic Toxicity: There is some evidence that dinoseb may be an oncogen based on significant treatment (but not dose) related liver adenomas in female mice and liver adenomas plus carcinomas in female mice but not in male mice. EPA has catergorized dinoseb as a Class C oncogen, i.e. a possible human oncogen. Nitrosomines, a potentially potent cancer causing agent are also present as contaminants in alkanolamine and triethanolamine salt formulations of dinoseb at levels between 0.6 and 279 ppm.

Dinoseb has the potential to damage human eyes according to studies which show dinitrophenols to induce cateracts in humans and similar effects in laboratory animals.

Limited studies also suggest that dinoseb has the potential to affect immunological systems based on studies in hamsters and mice. JMPR/Codex ADI: None

3.3 Environmental Characteristics:

3.3.1 Fate: Data on persistence is inadequate, but initial residues can be greater than 2000 ppm on short rangegrass, over 1000 ppm on long grass, leaves and leafy crops, over 500 ppm on forage and over 100 ppm on pod-containing seeds and large insects. These levels generally exceed the subacute dietary LC_{50} of non-target mammals. Estimated level in water from application to corn is 29 ppb which would exceed the maximum acceptable toxicant concentration (MATC) in water.

3.3.2 Effects: Highly toxic to birds, mammals and invertebrates. Residues occurring after application of dinoseb at maximum label rates have the potential to cause both acute and reproductive effects.

3.3.2.1 Mammals: Acute toxicity (LD_{50}s: rat-40 mg/kg; guinea pig-25 mg/kg; mouse-41 mg/kg). Reproductive impairment in mice occurs at 1 mg/kg/day which can be reached by a level of 7 ppm fodder residues as compared to the levels of residue of 500-1000 ppm expected from maximum label rates of application. These data indicate that both acute toxic effects and reproductive impairment in mammals are potential concerns.

3.3.2.2 Birds: Highly toxic to waterfowl and upland game birds. Acute toxicity (LD_{50}) is seen at levels of 11.5 mg/kg in mallard, 42.5 in bobwhite quail and LC_{50} of 515 ppm in ringnecked pheasants.

Concentrations expected from maximum label doses can exceed LC_{50} levels. Field kills of pheasants and songbirds have been attributed to dinoseb exposure.

3.3.2.3 Aquatic Organisms: Fish 96-hour LC_{50}s are 0.7 mg/l for fathead minnow, 0.067 mg/l for lake trout and 0.110 mg/l for 51 percent soluble concentrate/liquid triethanolamine salt formulation. MATC is 14.5 ppb which would be exceeded by the estimated environmental concentration of 29 ppb resulting from maximum label dose on corn.

Dinoseb is moderately toxic to juvenile estuarine invertebrates (pink shrimp 96-hour LC_{50}-1.96 mg/l) and highly toxic to the embryo-larvae stage of oysters (48-hour EC_{50}-0.209 mg/l).

3.4 Exposure:

3.4.1 Food: Dinoseb residues are rarely found in food and such residues as have been found in water have adequate margins of safety with respect to developmental toxicity. Dietary exposure poses a negligible risk.

3.4.2 Occupational/Use: Dinoseb appears to be readily absorbed through the skin. Estimates of worker (applicators, mixers, loaders, etc.) exposure based on field measurements, a NOEL of 3 mg/kg/day and assuming 100 percent dermal penetration show virtually no margin of safety for potential birth defects for women of child-bearing age even with use of state-of-the-art protective farm equipment.

Male applicators may be at risk of dinoseb induced adverse reproductive effects (temporary or permanent sterility) after an extended period of exposure.

3.4.3 Environment: As noted in Section 2 above, estimated concentrations resulting from applications at the maximum label dose are expected to result in immediate residues in forage and water which exceed the estimated maximum acceptable concentrations for mammals, birds and aquatic organisms. Bird kills observed in the field have been attributed to dinoseb exposure.

Although quantitative data are not available, dinoseb may pose a substantial risk of inducing birth defects in women exposed through spray drift or indirect routes such as contaminated clothing.

3.4.4 Accidental Poisoning: Poisoning incidents have been reported and at least one death of an applicator using an apparently leaking back-pack sprayer. Poisoning incidents resulting from environmental exposures through spray drift have also been reported.

3.5 Measures to Reduce Exposure: No measures to reduce exposure to workers have been determined to provide adequate margins of safety. Among the measures considered and rejected by the US were: protective clothing, reformulation, reduced application rates, restrictions on use by female workers and repackaging in water soluble bags.

3.6 Packaging and Labelling: Follow FAO Guidelines on Good Labelling Practice for Pesticides where use is permitted. However, packaging and labelling are unlikely to reduce the potential risks of dinoseb to those occupationally or environmentally exposed.

3.7 Waste Disposal Methods: Guidelines are under development. This section will be updated when guidelines are available.

3.8 Maximum Residues Limits. (mg/kg): JMPR/Codex Maximum Residue Limits: None

4. MAJOR REFERENCES

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ANNEX 1
SUMMARY OF CONTROL ACTIONS AND REMAINING USES FOR DINOSEB, AS REPORTED BY COUNTRIES

BANNED:

Colombia	(1987)	Banned as agricultural chemical.
Cyprus	(1987)	Banned as agricultural chemical.
Denmark	(1984)	Banned.
Ecuador	(1987)	Banned.
Finland	(1987)	Banned as agricultural chemical.
Great Britain	(1988)	Banned as agricultural chemical.
Hungary	(1988)	Banned as agricultural chemical.
Netherlands	(1990)	Banned as agricultural chemical.
Panama	(1987)	Banned as agricultural chemical.
Sweden	(1971)	Banned.
USA	(1986)	Banned.

WITHDRAWN:

None reported.

SEVERELY RESTRICTED:

Only remaining uses allowed:

None reported.

Specific uses reported as not allowed:

None reported.

Use permitted only with special authorization:

None reported.

ANNEX 2

ALTERNATIVES REPORTED FOR DINOSEB USES

UNITED STATES: In its regulatory decision documents, the U.S. Environmental Protection Agency (EPA) discussed possible alternatives for uses of dinoseb in the US on:

1. Soybeans: Used to control immature broad-leaf weeds. Alternatives include reliance on late post-emergence herbicides such as bentazon, acifluorfen and 2,4-DB. Some herbicides imazaquin (Scepto), Canopy and Classic will control some dinoseb-controlled weeds.

2. Peanuts: Used to control immature broad-leaf weeds. Alternatives include reliance on late application of post-emergence weed controls such as bentazon, acifluofen and 2,4-DB. Alternative pesticides are limited in number and do not provide the same weed control spectrum as dinoseb.

3. Cotton: Dinoseb used to control broad-leaf weeds that are not controlled by preplant-incorporated or pre-emergence herbicides. Post-emergence herbicides which may be used for broad-leaf weed control on cotton are cyanazine (may be tank mixed with MSMA or norflurazon), MSMA, DSMA, EPTC, linuron, oxyfluorfen, fluometuron, diuron and glysophate.

4. Snap Beans: Used on a selected basis to control annual weeds. Potential alternatives uncertain.

5. Potatoes: Used both as a herbicide (minor) and as a vine desiccant prior to harvest (principal use). Alternatives for desiccant use are diquat and paraquat for fresh market potatoes only.

6. Green Peas: Pre- and post-emergence control of broad-leaf weeds. Alternatives are bentazon, MCPA and MCPB. Alternatives provide poor control of black nightshade for which there are no good alternatives.

7. Grapes: Used for control of black nightshade, pig weed, purslane and other winter broad-leaf weeds, principally in California. Alternatives are glysophate, paraquat, diuron, simizine and napropamide.

Also used as a dormant spray to control dead-arm disease. For dormant vines the alternative is sodium arsenite; non-dormant vines may be treated with captan, basic copper sulfate, folpet and mancozeb, which provide adequate control of dead-arm disease.

8. Alfalfa: Used to control annual and perennial weeds and grasses and to desiccate seed crop before harvest. Major alternatives are propham, 2,4-DB, simazine, chloropropham, paraquat and diuron.

9. Almonds and Walnuts: Used for control of annual grasses and braodleaf weeds. Primary alternatives on walnuts are paraquat, simazine, diuron, EPTC, and oxyfluorfen. Primary alternatives on almonds are paraquat, glysophate, simazine and napropamide.

Dinoseb triethanolamine salt is also used as a fungicide for control of blossom brown rot disease. One alternative is sodium pentachlorophenate which is equally effective; other fungicides are available as direct leaf sprays.

10. Berries: Major use is on strawberries, raspberries and blackberries. Alternatives to control chickweed and annual winter grasses on strawberries are DCPA and napropamide. Alternatives to control annual grasses and broad-leaf weeds on other berries are mainly paraquat and diuron .

11. Hops: Use is to control or suppress downy mildew in combination with other fungicides. There appears to be no true alternative and growers will need to rely on other chemicals and modify their production systems.

NOTE: US consideration of alternatives takes into account the registration status of such alternatives in the US. Therefore, if a pesticide is not registered for the use at the time the control action is taken, it is not considered an alternative even though it could possibly be registered at a subsequent date. Contact the EPA Designated National Authority (DNA) for current information on alternatives approved in the US for any particular use.

Ed.1, July 1991