CS INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

Health and Safety Guide No. 94

BROMADIOLONE HEALTH AND SAFETY GUIDE

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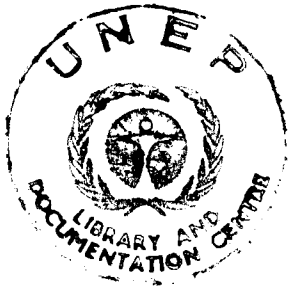
BROMADIOLONE HEALTH AND SAFETY GUIDE

This is a companion volume to
Environmental Health Criteria 175: Anticoagulant Rodenticides



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CONTENTS

INTRODUCTION

The Environmental Health Criteria (EHC) monographs produced by the International Programme on Chemical Safety include an assessment of the effects on the environment and on human health of exposure to a chemical or combination of chemicals, or physical or biological agents. They also provide guidelines for setting exposure limits.

The purpose of a Health and Safety Guide is to facilitate the application of these guidelines in national chemical safety programmes. The first three sections of a Health and Safety Guide highlight the relevant technical information in the corresponding EHC. Section 4 includes advice on preventive and protective measures and emergency action; health workers should be thoroughly familiar with the medical information to ensure that they can act efficiently in an emergency. Within the Guide is a Summary of Chemical Safety Information which should be readily available, and should be clearly explained, to all who could come into contact with the chemical. The section on regulatory information has been extracted from the legal file of the International Register of Potentially Toxic Chemicals (IRPTC) and from other United Nations sources.

The target readership includes occupational health services, those in ministries, governmental agencies, industry, and trade unions who are involved in the safe use of chemicals and the avoidance of environmental health hazards, and those wanting more information on this topic. An attempt has been made to use only terms that will be familiar to the intended user. However, sections 1 and 2 inevitably contain some technical terms. A bibliography has been included for readers who require further background information.

Revision of the information in this Guide will take place in due course, and the eventual aim is to use standardized terminology. Comments on any difficulties encountered in using the Guide would be very helpful and should be addressed to:

The Director
International Programme on Chemical Safety
World Health Organization
1211 Geneva 27
Switzerland

THE INFORMATION IN THIS GUIDE SHOULD BE CONSIDERED AS A STARTING POINT TO A COMPREHENSIVE HEALTH AND SAFETY PROGRAMME

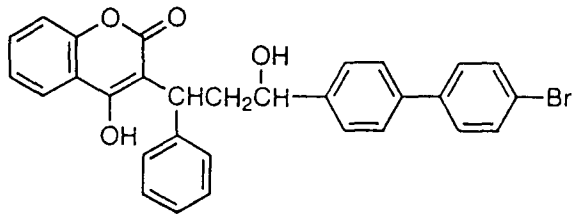
1. PRODUCT IDENTITY AND USES

1.1 Identity

Common name: bromadiolone

Chemical formula: $C_{30}H_{23}BrO_4$

Chemical structure:



Common synonyms: broprodifacoum

Trade names: Apobas; Bromard; Bromatrol; Bromorat; Contrac; Deadline; Hurex; Lanirat; Maki; Morfaron; Musal; Ramortal; Ratimon; Rodine-c; Slaymore; Super-caid; Toidon

CAS chemical name: 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2 one (9CI)

3-[-[*p*-(*p*-bromophenyl)-hydroxyphenethyl]-benzyl-4-hydroxycoumarin](8CI)

IUPAC chemical name: 3-[3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin

CAS registry number: 28772-56-7

RTECS registry number: GN4934700

1.2 Physical and Chemical Properties

Bromadiolone is a white to off-white powder. Its solubility in water is very low (less than 20 mg/litre at 20 °C). It is slightly soluble in ethanol and ethyl acetate, and soluble in dimethylformamide. The flash-point temperature is 218 °C.

Further physical and chemical properties of bromadiolone are given in the "Summary of Chemical Safety Information" (section 6).

1.3 Analytical Methods

The determination of bromadiolone is based on high-performance liquid chromatography with a detection limit of 0.01 mg/kg.

1.4 Production and Uses

The rodenticidal properties of bromadiolone were reported in 1976. It is an anticoagulant that is effective against rats and mice, including those resistant to first generation anticoagulants. It is used in the form of ready-to-use baits of low concentration containing 0.005% bromadiolone.

2. SUMMARY AND EVALUATION

2.1 Identity, Physical and Chemical Properties, and Analytical Methods

Bromadiolone is a white to off-white powder. It is stable at room temperature and has a melting point of 200-210 °C. Its solubility in water is very low. It is slightly soluble in ethanol and ethyl acetate, and soluble in dimethylformamide. The determination of bromadiolone is based on high-performance liquid chromatography.

2.2 Sources of Human and Environmental Exposure

Bromadiolone does not occur naturally. It is used as a rodenticide in urban and farm rodent control and acts by disrupting the normal blood clotting mechanisms causing an increased tendency to bleed.

2.3 Environmental Transport, Distribution, and Transformation

Bromadiolone is unlikely to enter the atmosphere, because of its low volatility. It is practically insoluble in water. Bromadiolone is readily adsorbed on soils rich in clay and organic compounds, with no leaching. Degradation in soil is significant with half-lives ranging from 1.8 to 7.4 days.

2.4 Environmental Levels and Human Exposure

Bromadiolone is not intended for direct application to growing crops and never for use as a food additive.

No information is available on concentrations in air, water, and soil.

2.5 Kinetics and Metabolism in Laboratory Animals and Humans

Bromadiolone is absorbed through the gastrointestinal tract, skin, and respiratory system. The major route of elimination in different species after oral administration is via the faeces. The liver is the main organ of accumulation and storage. Bromadiolone has been found in the liver as the unchanged parent compound. Elimination from the liver is biphasic with an initial rapid phase of 2-8 days and a slower phase with a half-life of

170 days. No data are available on the kinetics and metabolism of bromadiolone in humans.

2.6 Effects on Laboratory Mammals and *in vitro* Test Systems

Bromadiolone has a high, acute oral toxicity (LD_{50} of 1-3 mg/kg) for various species including rodents and non-rodents. The dermal toxicity is also high (LD_{50} of 9.4 mg/kg in rabbits). Signs of poisoning are those associated with an increased tendency to bleed.

Bromadiolone is non-irritant to the skin. It is a slight irritant for the eye.

In feeding studies on rats, the only effect found has been that associated with anticoagulant action. In a 12-week feeding study on rats, the maximum tolerated dose was 10 μg/kg body weight per day.

Mutagenicity and teratogenicity studies have not shown any mutagenic, embryotoxic, or teratogenic effects.

2.7 Effects on Humans

Symptoms of acute intoxication by bromadiolone include an increased tendency to bleed in less severe cases of poisoning, and massive haemorrhaging in more severe cases. The signs of poisoning develop with a delay of one to several days after ingestion.

Incidents of poisoning have been reported.

2.8 Effects on Other Organisms in the Laboratory and Field

Bromadiolone has shown toxicity for aquatic organisms. The LC_{50} (96-h) for various fish species ranged from 1.4 to more than 3 mg/litre.

Bird species appear to be less susceptible to bromadiolone than mammals with a reported acute, oral LD_{50} of at 138 mg/kg.

Secondary poisoning through the consumption of rats and mice killed with bromadiolone may occur in dogs and cats in urban situations, but more likely in farm situations.

2.9 Evaluation of Human Health Risks and Effects on the Environment

2.9.1 *Evaluation of human health risks*

As bromadiolone is mainly used in urban rodent control in the form of low-concentration baits, increased levels in air are unlikely. Furthermore, as it is only slightly soluble in water, its use cannot be a significant source of water contamination. Bromadiolone is not intended for direct application to growing crops and no residues in plant food-stuffs are expected. Occupational exposure may occur during manufacture, formulation, and bait application, but data concerning the levels of exposure are not available. Bromadiolone may be absorbed through the gastrointestinal tract and also through the skin. The major route of elimination is via the faeces. The liver is the major organ for the accumulation of bromadiolone, which has mainly been found as the unchanged parent compound. Elimination from the liver is slow.

As a technical material, bromadiolone is extremely toxic for many mammalian species. Signs of poisoning in all species, including humans, are associated with an increased tendency to bleed.

Incidents of poisoning have been reported.

The level of prothrombin time is a satisfactory guide to the severity of acute intoxication, and also the effectiveness and duration of the therapy.

The specific antidote is vitamin K_1 in both animals and man (see section 4.1.1).

2.9.2 *Evaluation of effects on the environment*

Bromadiolone is applied to discrete sites in the form of low-concentration baits and is stable under normal conditions. Bromadiolone is poorly soluble in water and, in a bait formulation, it is is unlikely to be a source of water pollution. As a technical material, it is toxic for aquatic organisms.

Bromadiolone is readily adsorbed on soil, rich in clay and organic compounds, with no leaching; degradation in soil is significant.

SUMMARY AND EVALUATION

Non-target organisms are potentially at risk from direct consumption of baits (primary hazard) and through eating poisoned rodents (secondary hazard).

Whole-grain baits are highly attractive to birds. Bird species appear to be less susceptible to bromadiolone than rodents.

The primary hazard is usually expressed by the amount of finished bait that must be consumed to approach the lethal dose. To reach the toxic or lethal dose, the non-target species must consume comparatively large amounts of bait with a concentration of 0.005% active ingredient.

Some secondary toxicity laboratory studies on wildlife have shown that captive predators could be intoxicated by no-choice feeding of bromadiolone-poisoned or dosed prey. The significance of these results in terms of hazards under field conditions is difficult to assess, because the predators would not be expected to eat only poisoned animals. However, predators may take poisoned small mammals that are still alive, preferentially. In areas close to baiting, poisoned rodents may represent a high proportion of the diet for individual birds. However, only few individuals will be affected, unless there is very widespread and constant use of the baits.

Therefore, some kills of owls can be expected, but there will be no severe population effects. This ties in with small numbers of poisoned owls observed in the field.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

Exposure of the general population to bromadiolone through air, drinking-water, or food is unlikely and does not constitute a significant health hazard. Poisoning incidents may occur in cases of massive intentional, or unintentional, ingestion, or prolonged exposure during manufacture and formulation.

Bromadiolone is relatively persistent in the environment, but its specific use as low-concentration bait formulations cannot be a significant source of air, water, soil, and food contamination. Direct and secondary poisoning of birds, domestic and farm animals, and wildlife may occur.

3.2 Recommendations for the Protection of Human Health and the Environment

Potentially exposed workers should receive appropriate biomonitoring and health evaluation.

To prevent primary poisoning, baits should be placed where they cannot be readily available to non-target species, e.g., in bait stations.

Killed rodents should be burned or buried to prevent secondary poisoning in predators.

4. HUMAN HEALTH HAZARDS, PREVENTION AND PROTECTION, EMERGENCY ACTION

4.1 Human Health Hazards, Prevention and Protection, First Aid

The oral toxicity of bromadiolone for mammals is extremely high (rat oral LD_{50}, 1.12 mg/kg; rabbit oral LD_{50}, 1 mg/kg). The dermal toxicity is also very high (rabbit LD_{50} 9.4 mg/kg). No definite toxic dose has been established for humans, because of the limited clinical reports available.

The main features of bromadiolone poisoning in less severe cases are excessive bruising, nose and gum bleeding, and blood in the urine and faeces. Bleeding from several organs within the body leading to shock and possibly death occurs in more severe cases. The onset of the signs of poisoning may not be evident until one to several days after ingestion.

Bromadiolone is non-irritant to the skin, but is slightly irritant to the eye.

Bromadiolone is slowly metabolized by mammals and may accumulate in the liver reaching toxic levels with repeated exposure.

Handling of technical material or powder concentrates will require the use of full air-fed protection and an impervious suit, suitable for wash-down. In operations with liquid concentrates, PVC or nitrile-rubber gloves, armlets, and an apron should be worn together with a face shield and rubber boots.

All persons who are bleeding must obtain medical attention.

4.1.1 *Advice to physicians*

If poisoning has occurred recently (within a few hours), gastric lavage and the administration of charcoal in repeated doses is recommended.

A venous blood sample should be taken to measure the haemoglobin level, prothrombin time, blood grouping, and cross-matching.

If a patient is bleeding severely, 25 mg of vitamin K_1 (phytomenadione) should be given by slow intravenous injection. The patient should be transfused with whole blood or plasma. Fresh, frozen plasma may be given. Prothrombin time should be checked at 3-h intervals and injections of vitamin K_1 repeated, if no improvement occurs. Administration of factor concentrate may be considered to avoid volume overload.

In less severe cases of poisoning, vitamin K_1 may be given in lower doses together with fresh, frozen plasma for rapid restoration of blood clotting factors. Prothrombin time should be checked after 8-10 h and vitamin K_1 administration repeated, if necessary.

Once the prothrombin time has stabilized, treatment with oral vitamin K_1 (10 mg) should be continued four times daily. Oral treatment may be sufficient in minor cases.

The patient should be kept in hospital until the prothrombin time has remained normal for three days.

The patient should be discharged from hospital with the following treatment: oral vitamin K_1 (10 mg) twice daily for up to 60 days with close monitoring of the prothrombin time. It may be possible to reduce the length of treatment.

4.1.2 *Health surveillance advice*

Workers handling concentrates must undergo periodic determination of the potential disturbances of the clotting mechanisms, using the most appropriate method, i.e., by measuring circulating descarboxy-prothrombin, prothrombin concentration, or prothrombin time.

4.2 Explosion and Fire Hazards

High temperature decomposition or burning in air will lead to the formation of toxic gases, which may include carbon monoxide and traces of bromine and hydrogen bromide, as well as fumes of unchanged rodenticide; breathing apparatus must be worn in fire fighting.

Heating of containers will cause a pressure rise, with the risk of bursting and subsequent ignition. Fire-exposed containers should be kept cool by spraying with water.

Extinguishers recommended for small fires are carbon dioxide or dry powder; foam or water fog are recommended for larger fires. A water jet should not be used.

Run-off water from the fire should be prevented from entering surface-water drains or water sources.

4.3 Storage

Technical material and formulations should be stored in sealed containers in locked, well-ventilated, dry areas, away from frost, direct sunlight, and sources of heat and ignition. Keep products out of reach of children and unauthorized personnel. Do not store near food or animal feed.

4.4 Transport

Comply with local regulations regarding the movement of hazardous goods. Before despatch, ensure that the containers are sound and that labels are securely fixed and undamaged.

4.5 Spillage

During decontamination, the operator must wear protective clothing, PVC gloves, a face shield, and rubber boots.

Dry spillages should be collected at once, by suction, and disposed of as toxic waste according to local legislation.

Liquid spillages should be adsorbed onto vermiculite or other inert adsorbent and treated similarly.

Contaminated areas should be washed down with cold water containing surfactant; the washings must be prevented from entering surface-water drains.

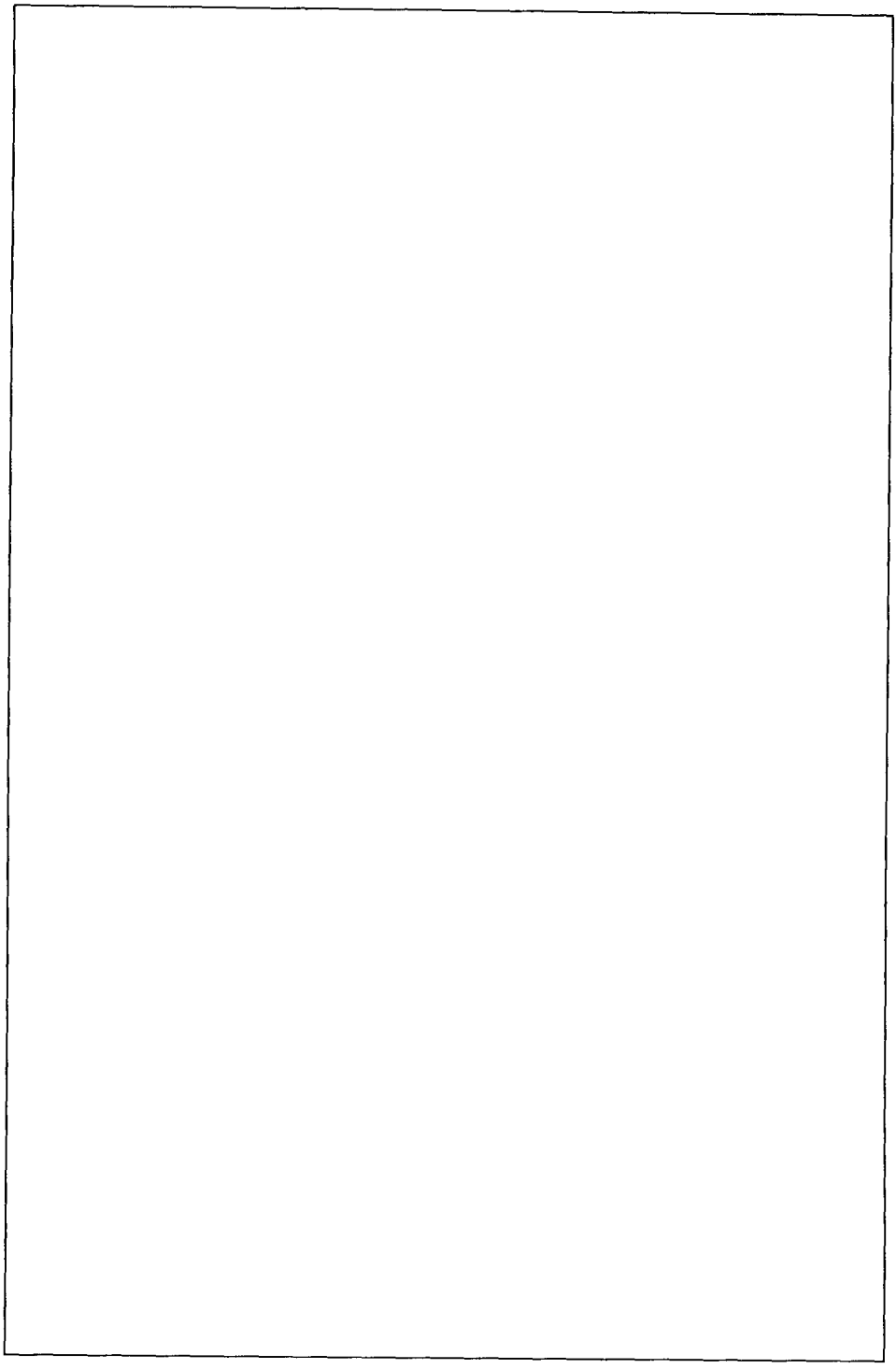
4.6 Disposal

Disposal should be carried out according to national regulations.

5. HAZARDS FOR THE ENVIRONMENT AND THEIR PREVENTION

Bromadiolone is stable but rapidly binds on the soil with very slow desorption and without leaching. Bromadiolone is slightly soluble in water and, in the form of bait-formulations, it is unlikely to be a source of water contamination.

Do not place baits where domestic or farm animals and birds can reach them. Burn or bury any uneaten bait. Do not dump it in water. Look for dead rats and mice and burn or bury them.



6. SUMMARY OF CHEMICAL SAFETY INFORMATION

This summary should be easily available to all health workers concerned with, and users of, bromadiolone. It should be displayed at, or near, entrances to areas where there is potential exposure to bromadiolone, and on processing equipment and containers. The summary should be translated into the appropriate language(s). All persons potentially exposed to the chemical should also have the instructions in the summary clearly explained.

Space is available for insertion of the National Occupational Exposure Limit, the address and telephone number of the National Poison Control Centre, and local trade names.

SUMMARY OF CHEMICAL SAFETY INFORMATION

BROMADIOLONE

Chemical formula: $C_{30}H_{23}BrO_4$

CAS chemical name:3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2 one (9CI)

IUPAC chemical name: 3-[3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin

CAS registry number: 28772-56-7

RTECS number: GN4934700

PHYSICAL PROPERTIES

Physical state	powder
Colour	off-white
Relative molecular mass	527.4
Melting point (°C)	200-210
Vapour pressure (20 °C)	2×10^{-6} Pa
Solubility in water at 20 °C	19 mg/litre
Solubility in	
dimethylformamide	730 g/litre
ethanol	8.2 g/litre
ethyl acetate	25 g/litre

OTHER CHARACTERISTICS

Bromadiolone is an anticoagulant rodenticide; it is formulated as low-concentration baits (usually 0.005% active ingredient)

HAZARD /SYMPTOMS	PREVENTION AND PROTECTION	FIRST AID
GENERAL: Readily absorbed following ingestion or inhalation, or through the skin; if absorbed, effects may range from an increased tendency to bleed to massive haemorrhaging	Avoid exposure	Obtain medical attention; antidote - vitamin K_1
SKIN: Non-irritant; skin absorption may occur from liquid concentrate	Wear gloves when handling concentrate	Wash with soap and water; seek medical attention
EYES: Slight irritant	Use face shield when handling concentrate	Flush eyes with water for at least 15 min
INHALATION: Significant vapour exposure unlikely	Avoid inhaling concentrate aerosols or bait dust	Obtain medical attention, if necessary
INGESTION: An unlikely occupational hazard	Wash hands before eating, drinking, or smoking	Transfer to hospital immediately; rinse out the mouth with water
Accidental or intentional ingestion may lead to poisoning in several hours or days	Keep out of reach of children, under lock and key	

SUMMARY OF CHEMICAL SAFETY INFORMATION (*continued*)

SPILLAGE	STORAGE	FIRE/EXPLOSION
Wear protective clothing during decontamination; dry spillage - collect and dispose of as toxic waste; liquid spillage - absorb on vermiculite or other inert absorbent and treat similarly; do not contaminate surface-water drains	Store in sealed containers in a dry, ventilated, and locked storeroom, away from children, unauthorized persons, and domestic animals, food, and animal feed	Combustible solid; burning in air will lead to the formation of toxic gases; for small fires, use carbon dioxide, halons, or dry powder; for larger fires, use foam or water fog; keep containers cool by spraying with water

WASTE DISPOSAL	NATIONAL INFORMATION
Proper incineration is the method of choice	

7. CURRENT REGULATIONS, GUIDELINES, AND STANDARDS

7.1 Previous Evaluations by International Bodies

Bromadiolone (technical) has been classified by WHO in Class Ia - Extremely Hazardous, based on the acute oral LD_{50} of 1.12 mg/kg for rats.

7.2 Exposure Limit Values

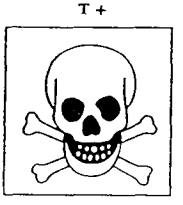
No information is available.

7.3 Specific Restrictions

Bromadiolone has been approved for use as a rodenticide in many countries. In some countries, specific uses are defined, as well as limitations and precautions.

7.4 Labelling, Packaging, and Transport

The European Economic Community legislation requires labelling of technical brodifacoum as very toxic with a hazard symbol T+ and the following pictogram:



VERY TOXIC

The United Nations in its Recommendations on the Transport of Dangerous Goods classified bromadiolone in Category 6.1 as a poisonous substance (No. 3027).

R26/27/28	Very toxic by inhalation, contact with the skin and by ingestion.
R48	Risks of serious effects to health in case of prolonged exposure.

CURRENT REGULATIONS, GUIDELINES, AND STANDARDS

7.5 Waste Disposal

No specific information is available.

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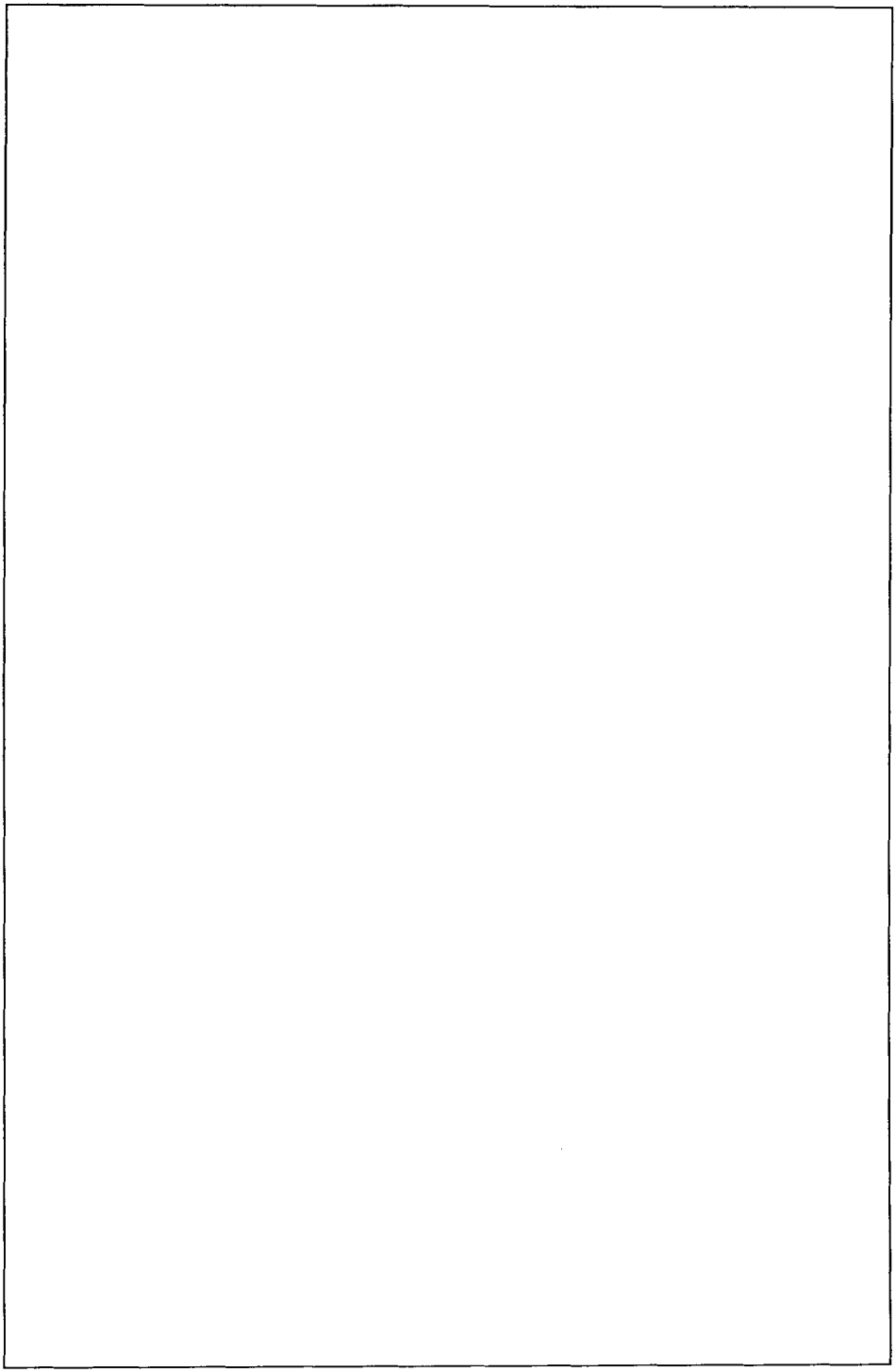

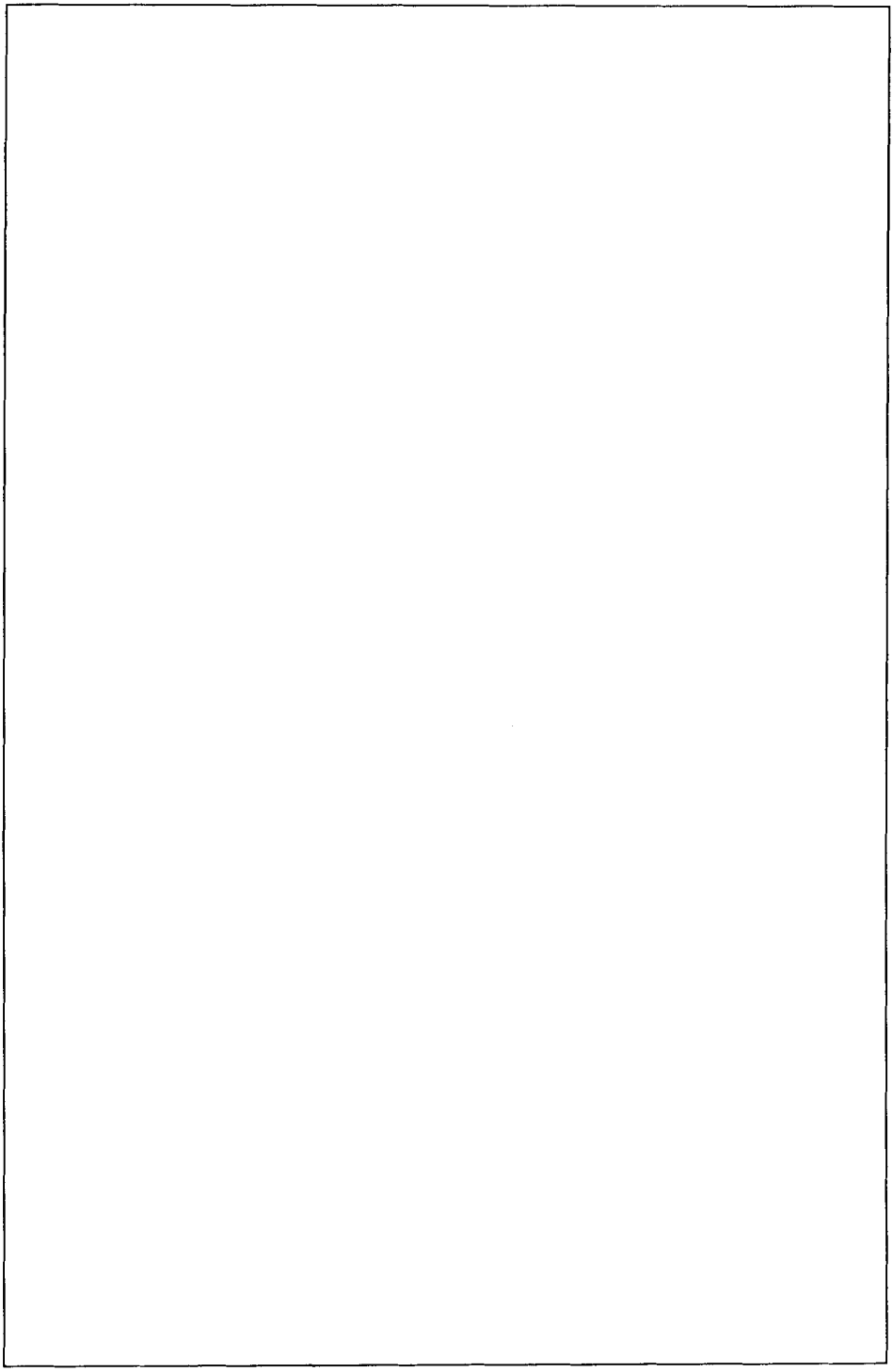

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Tetradifon (No. 11, 1987)
Tetramethrin (No. 31, 1989)
Tri-allate (No. 89, 1994)
Trichlorfon (No. 66, 1991)
Trimellitic anhydride (No. 71, 1992)
Vanadium (No. 42, 1990)
Vinylidene chloride (No. 36, 1989)

Price: Sw. fr. 5.-
Price in developing countries: Sw. fr. 3.50

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