SAFETY DATA SHEET

DRAKER 10.2

In accordance with Regulation (EC) 1907/2006, (EC) 1272/2008 and (EU) 453/2010 (Annex I)

SECTION 1.
IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1. Mixture identifier

Mixture name:	**DRAKER 10.2**

1.2. Relevant identified uses of the mixture and uses advised against

Relevant use(s)	Concentrated microencapsuled insecticide for surfaces and room spray "Presidio medico chirurgico" product requiring Italian Ministry of Health approval for sale N. 19380
Uses advised against	Other uses are not expected.

1.3. Details of the supplier of the safety data sheet

Manufacturer: VEBI Istituto Biochimico S.r.l.
Via Desman, 43
35010 S. Eufemia di Borgoricco (PD) Italy
Tel. +39 0499337111
Fax. +39 0495798263

e-mail MSDS manager: info@vebi.it

1.4. Emergency telephone number

Emergency number of the company and/or official advisory body:
Milano Niguarda +39 0266101029 (Milan)
Roma Ospedale Gemelli +39 063054342 (Rome hospital)
Napoli Ospedale Caldarelli +39 0815453333 (Naples hospital)
Catania Ospedale Garibaldi +39 095767594120 (Catania hospital)

SECTION 2
HAZARDS IDENTIFICATION

2.1 Classification of the mixture

in accordance with Directive 1999/45/EEC	in accordance with Regulation n. 1272/2008/EC
Xi, R43 **N, R50/53**	**Skin Sens. 1, H317** **Aquatic Acute 1, H400** **Aquatic Chronic 1, H410**

Main adverse effects
Physico-chemical effects Not foreseen
Health effects Ingestion: May cause adverse effects if swallowed.
Contact with skin: May cause sensitization by skin contact.
Contact with eyes: May cause irritation.
Inhalation: May cause irritation, cough, sore throat.
Environmental effects Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

See also sections from 9 to 12

2.2 Label elements

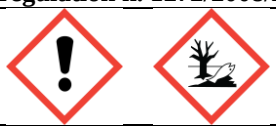
- **Labelling in accordance with Directive 1999/45/EEC**

Hazards symbols	

	Xi - Irritant N - Dangerous for the evironment
Risk phrases (R)[1]	**R43, R50/53**
Safety phrases (S) [1]	**S2, S24, S28, S37, S46, S61**

[1] For the explanation of R and S phrases: see Section 16

- **Labelling in accordance with regulation n. 1272/2008/EC**

Pictograms	
Signal Word	**Warning**
Hazard indication (H)[1]	**H317, H400, H410**
Safety statements (P)[1] -General - *Prevention* - *Reaction* - *Storage* - *Disposal*	 **P102** **P273, P280** **P302 + P352, P333 + P313** - **P501**

[1] For the explanation of H and P statements: see Section 16

2.3 Other hazards (which do not results in the classification)

The mixture satisfy the PBT criteria	YES	NO
- PBT		X
- vPvB		X

- Health hazards: May cause sensitization by skin contact.
- Environmental hazards: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- Physico-chemical hazards: Substance can emit toxic fumes in case of fire.
- Specific effects: There are no other specific effects.

SECTION 3
COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients

Name	EINECS/ ELINCS Number	CAS n.	Conc. % (w/w)	Classification (67/548/CEE)	Classification (1272/2008/EC)	Occupation Exposure Limits
Cypermethrin cis/trans +/− 40/60; (*) (Index n° 607-421-00-4)	257-842-9	52315-07-8	10 %	Xn; R20/22 Xi; R37 N; R50-53	Acute Tox. 4 *, H332 Acute Tox. 4 *, H302 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	See section n° 8
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1) (*) (Index n° 613-167-00-5)	-	55965-84-9	<0.1%	T; R23/24/25 C; R34 R43 N; R50-53 Specific Conc. Limits: C; R34: C ≥ 0,6 % Xi; R36/38: 0,06 % ≤ C < 0,6 % R43: C ≥ 0,0015 %	Acute Tox. 3 (*), H331 Acute Tox. 3 (*), H311 Acute Tox. 3 (*), H301 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Specific Conc. Limits: Skin Corr. 1B; H314: C ≥ 0,6 % Skin Irrit. 2; H315: 0,06 % ≤ C< 0,6 % Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6 % Skin Sens. 1; H317: C ≥ 0,0015 %	

Tetramenthrin	231-711-6	7696-12-0	2%	N; R50-53	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	
Piperonyl butoxide	200-076-7	51-03-6	10 %	N; R50-53	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	

SECTION 4
FIRST AID MEASURES

4.1 Description of the first aid measures

- *Eye contact* — Wash immediately with large amounts of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear and show this safety data sheet.
- *Skin contact* — Remove contaminated clothes and shoes immediately. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical advice if adverse symptoms appear and show this safety data sheet. Do not use solvents or thinners.
- *Ingestion* — If swallowed and if victim is conscious and alert wash mouth with water. Treat symptomatically and supportively. Get medical advice if adverse symptoms appear and show this safety data sheet.
- *Inhalation* — Remove patient from the contaminated area immediately and keep at rest in a well-ventilated area. Get medical advice.

4.2 Most important symptoms and effects (acute and delayed)

- *Acute effects* — INHALATION: May cause irritation, cough, sore throat.
SKIN: May cause redness and irritation. May cause sensitization by skin contact.
EYES: May cause redness, stinging sensation and irritation.
INGESTION: May cause negative effects if swallowed.
Cypermethrin and Tetramethrin are pyrethroid compounds.
Symptoms associated with exposure to pyrethroid compounds include skin and eye irritation, irritability to sound or touch, abnormal facial sensation, sensation of prickling, tingling, or creeping on skin, numbness, headache, dizziness, nausea, vomiting, diarrhea, salivation, and fatigue. At very high levels of exposure, muscle twitching and fluid accumulation in the lungs may occur. Shortness of breath, blisters, welts, and hives are also noted with tetramethrin exposure.[(12)] In mammals, tremor (T-syndrome) is the characteristic poisoning symptom with Tetramethrin. [(9)]
- *Delayed effects:* — Delayed effects and symptoms related to this mixture are not foreseen.

4.3 Indication of any immediate medical attention and special treatment needed

- *Medical monitoring:* — To be undertaken in case of delayed effects known.
- *Antidotes, if known* — Unknown.
- *Contraindications* — Unknown.
- *Immediate treatment at workplace* — SKIN : Rinse and the wash skin with water and soap.
EYES: First rinse with plenty of water for several minutes then take to a doctor.
INGESTION: Rinse mouth. Refer for medical attention.
INHALATION: Move person to fresh air. Refer for medical attention.

SECTION 5
FIREFIGHTING MEASURES

5.1 Extinguishing media

- *Suitable estinguishing media* — Water mist or spray, regular foam, CO_2, dry powder.
- *Unsuitable estinguishing media* — Unknown

5.2 Special hazards arising from the mixture

- *Hazardous combustion products*	May produce toxic fumes of CO_X, NO_X , SO_X, HCl,
- *Other special hazards*	Special hazards related to this substance are not known.

5.3 Advice for firefighters

- *Technical actions for protection*	Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.
- *Special protective equipment for firefighters*	Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must conform with EN standard and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6
ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Ventilate areas. Remove all sources of ignition and heat.

For emergency responders:

Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions

In case of accidental release in the environment prevent the substance from reaching drains, surface water and ground water. If the mixture has entered waterways, sewers or has contaminated the soil or the vegetation, notify the competent authorities.

6.3 Methods and material for containment and clearing up

- *Containment procedures:*	Collect all of the material scattered on the ground with suitable protective equipment and put it in a clean and dry container. Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8.
- *Cleaning up procedures:*	Recover the substance by scooping up or vacuum, or with other suitable mechanical means and wash the area with plenty of water. Store the recovered product until it can be disposed of in accordance with all regulations and at a properly accredited facility. If the spill happened on a highway, or in a public place, take all measures necessary in order to protect people from any risk.

6.4 Reference to other sections

See also section 8 and 13.

SECTION 7
HANDLING AND STORAGE

7.1. Precautions for safe handling

- *Recommendation for handling:*	Handle away from sparks and flames and all sources of ignition. Handle in a well ventilated place. Suitable containment system must be adopted to prevent dispersion of vapour that could be released during handling. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see Section 8). Keep the mixture away from drains, surface or ground waters.
- *Recommendation for personal hygiene:*	Do not eat, drink and smoke in the working areas. Wash hands after handling the mixture.

Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Condition for safe storage including any incompatibilities

The risk management procedures described in this section are consistent with the physical and chemical properties reported in section 9.
The mixture is not classified for any physical and chemical properties and no risk management is foreseen.

Risk Management measures related to:

- *Evaporative conditions:* Keep containers tightly closed and labelled with the name of the product. Containers of this material may be hazardous when empty since they retain product residues (vapours, liquids).
- *Potential ignition sources:* Don't expose to heat sources. Store separately from reactive or combustible materials.

Procedure to control other effects

- *Weather conditions:* Don't expose to high temperatures.
- *Ambient pressure:* No restrictive procedure expected.
- *Temperature* Store at room temperature.
- *Sunlight:* Avoid light and sunlight exposure.
- *Humidity:* Avoid humidity exposure

The adoption of the Risk Management procedure related to the physical and chemical properties is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the mixture), particularly when a standardized exposure scenario is not available (ingredients in the mixture are not yet REACH registered).

Material to keep the integrity of the mixture

- *Stabilisers:* Not involving the use of stabilizers.
- *Antioxidants:* Not involving the use of antioxidants.

Other advice

- *Ventilation requirements* Request based on the storage of the mixture.
- *Specific design of storage rooms* Not required on the basis of the classification.
- *Quantity limits for storage* Not required on the basis of the classification.
- *Packaging compatibilities* See also 10.5.

7.3. Specific end use(s)

- Recommendation for specific final use(s)

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X
- Industry or sector specific guidance available and attached		X

SECTION 8
EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

- National/European Occupational Exposure Limits	Not established
- Other Occupational Exposure Limits	Not established
- National/European Biological Limits (BEI):	Not established
- Other National/European Biological Limits (BEI):	Not established
- Recommended monitoring procedures	The measurements of the substance/s in the workplace must be carried out in accordance with standardized methods described by EN standard.
- DNEL values (components)	Chemical Safety Report has not been compiled.
- PNEC values (components)	PNEC freshwater = 0.003 mg/L, related to Piperonyl butoxide [(14)] PNEC marine water = 0.0003 mg/L, related to Piperonyl butoxide [(14)]

PNEC sediment (freshwater) = 0.0194 mg/kg sediment dw, related to Piperonyl butoxide [14]
PNEC sediment (marine water)= 0.00194 mg/kg sediment dw, related to Piperonyl butoxide [14]
PNEC soil = 0.136 mg/kg soil dw, related to Piperonyl butoxide [14]
PNEC oral = 12.53 mg/kg food , related to Piperonyl butoxide [14]

8.2. Exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

8.2.1. Appropriate engineering controls

The adoption of the most appropriate engineering controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the mixture), particularly when a standardized exposure scenario is not available (ingredients in the mixture are not yet REACH registered)

8.2.2. Individual **protection** *measures, such as Personal Protective Equipment (PPE)*

The adoption of the most appropriate Personal Protective Equipment is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the mixture), particularly when a standardized exposure scenario is not available (ingredients in the mixture are not yet REACH registered).
If the results of such risk evaluation done in accordance with Directive 98/24/EEC showed that the collective and general risk management measures are not sufficient to reduce the risks and, if the exposure to the mixture cannot be reduce by other containment means, appropriate PPE must be adopted in compliance with technical EN guidance indication.

a) Eye and Face protection	Safety goggles as for EN 166; facial shield or mask with approved filter.
b) Skin protection	
- hands protection	Gloves resistant to chemical agents as for the EN 374, parts 1, 2 and 3 and the European Directive 89/89/CEE (classified substances). The gloves material must be waterproof and stable against the mixture content. Use Polyvinyl alcohol or nitrile rubber gloves.
- other, body protection	Select the suitable protective equipment based on the activity of use and possible.
c) Respiratory protection	Special protections are not needed during the normal use of the product.

8.2.3 Environmental exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 9
PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Liquid
Odor:	Characteristic
Color:	Opalescent
pH:	5 – 5.5
Flash point:	Not determined
Boiling range:	Not determined
Melting point:	Not determined
Density:	1.00 – 1.05 mg/ml
Water solubility:	Dispersible
Partition coefficient	Not determined

Octanol/water ($logP_{OW}$):
Viscosity: Not determined

9.2. Other information

Data not available in the literature search carried out.

SECTION 10
STABILITY AND REACTIVITY

10.1. Reactivity

This substance is considered not reactive under the normal conditions of the usage.

10.2. Chemical stability

The mixture is stable at the normal condition of temperature and pressure and if stored in closed containers in well ventilated and cool place.

	NO	YES	Used stabiliser
- Stabilisers:	X	-	
- Change in physical appearance	X	-	
- Other hazards (temperature, pressure)	X	-	

10.3. Possibility of hazardous reactions

Under normal conditions of storage and use:

	NO	YES
- Possibility of an exothermic reaction:	X	-
- Possibility of a reaction releasing excessive pressure	X	-
- Possible degradation with instable product formation	X	-

10.4. Condition to avoid

Keep away from hot temperatures, ignition sources, from water and humidity and from light.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

If heated at high temperatures, decomposes releasing fumes and toxic gases of CO_X, NO_X , SO_X, HCl,

SECTION 11
INFORMATION ON TOXICOLOGICAL EFFECTS

- Exposure routes:	YES	NO
- Inhalation:	X	
- Ingestion:	X	
- Skin contact:	X	
- Eye contact:	X	

- Effects (acute, delayed, chronic) following the exposure (short and/or prolonged):

- *Ingestion:* Characteristic taste. May cause negative effects if swallowed.
- *Skin contact:* May cause redness and irritation. May cause sensitization by skin contact.
- *Eye contact:* May cause redness, stinging sensation and irritation.
- *Inhalation:* May cause irritation, cough, sore throat.

Mixture contains Cypermethrin and Tetramethrin, that are pyrethroid compounds.

- **Toxico-kinetics information (ADME = Adsorption, Distribution, Metabolism, Excretion):**

When radioactive pyrethroid is administered orally to mammals, it is absorbed from intestinal tract of the animals and distributed in every tissue examined. (8)

Cypermethrin is primarily absorbed from the gastrointestinal tract. It may a so be absorbed by inhalation of spray mist and only minimally through the intact skin. Both isomers are readily metabolized by liver microsomal esterases and oxidases. The cis -isomer is the more stable of the two and may undergo extensive hydroxylation prior to ester cleavage. In most animals, except dogs, urine was the major route of elimination (+80%). In rats and mice, only a small amount of unhydrolysed product was found in faeces. Elimination of cypermethrin was rapid in most animals, in most tissues the half-life was approximately one day; in adipose tissue it ranged from 10 to 30 days. (1)

In rats, tetramethrin radiolabelled in the acid or alcohol moiety is readily taken up, metabolized, and excreted after oral or subcutaneous administration. Approximately 95% is excreted in 5-7 days in the urine and faeces in more or less equal amounts. The tissue residues from both administration routes are very low. (9)

In an in vivo study on rat, absorbed Piperonyl Butoxide appears to be quantitatively degraded since little or no parent material was found in the urine. Piperonyl Butoxide was extensively metabolized, the major route of metabolism being the opening of the methylenedioxy ring followed by the sequential oxidation of the 2-(2-butoxethoxy)ethoxymethyl side chain. Bioaccumation of the substance or its degradates in tissues is unlikely following oral administration of 14C piperonyl butoxide. (14)

N-methyl malonamic acid was detected as the main metabolite in the urine of rats given oral doses of either of the two isothiazolones. Malonamic acid and malonic acid were also identified as metabolites. (15)

- Acute toxicity effects:

- *Oral:* LD_{50} female rat = 891mg/kg for Cypermethrin of cis:trans isomer ratio 40:60. The toxic signs were characterised by salivation, increased startle response, ataxia, splayed gait, tremors and convulsions. (2) LD50 also varies from 367 to 2000 mg/kg in female rats, and from 82 to 779 mg/kg in mice, depending on the ratio of cis/trans-isomers present (3)
  LD_{50} rat = 4640 mg/kg for Tetramethrin (10)
  LD_{50} rat = 5630 mg/kg for Piperonyl Butoxide (14)
  LD_{50} (rat) = 53 mg/kg (Somnolence, general depressed activity, ataxia, respiratory depression), for Reaction mass of isothiazolones (CAS 55965-84-9) (16)
- *Dermal:* LD_{50} rat > 1600 mg/kg for Cypermethrin (3)
  LD_{50} rabbi t > 2400 mg/kg for Cypermethrin (17)
  LD_{50} rat > 2500 mg/kg for Tetramethrin (10)
  LD_{50} rabbit > 2000 mg/kg for Piperonyl Butoxide (14)
  LD_{50} (rat) = 80 mg/Kg, for Active isothiazolones (15)
- Inhalation: LC_{50} rat = 7889 mg/m3/4 hour for Cypermethrin (4)
  LC_{50} rat > 2500mg/m3/3H for Tetramethrin (10)
  LC_{50} rat = > 5.9 mg/l/4h for Piperonyl Butoxide (14)
  LC_{50} (rat) = 650 mg/m3/4 hours for Active isothiazolones (15)

- Corrosion/Irritation effects: Moderate skin irritation and mild eye irritation were produced by single applications of undiluted technical cypermethrin in rabbits. (1)

In a semi-closed patch test, an aqueous emulsion containing 1.0% tetramethrin was applied to the skin of 200 human volunteers for 4 days. Dermatological examination showed that tetramethrin is neither a primary irritant nor a human skin sensitizer. In an eye irritation study on rabbits, with 0.1 ml tetramethrin (technical grade, 95.6% purity), the irritating potency of the material was judged to be minimal. (9)

Piperonyl Butoxide resulted not irritating to the skin and eyes of rabbits in two acute Dermal Irritation/Corrosion (OECD Guideline 404), and respectively Eye Irritation/Corrosion (OECD Guideline 405) studies. (14)

- Severe ocular lesion *:* Data not available in the literature search carried out.

- Sensitization:

- *Dermal:* Cypermethrin was observed to have a weak sensitization potential in guinea-pigs. (1)
  In a skin-sensitization study of tetramethrin in guinea-pigs, no skin sensitization reaction was noted (8)
  The Mixture of isothiazolones showed sensitizing power. (1)
  Piperonyl Butoxide doesn't appear to be a dermal sensitizer to albino guinea pigs,

under the conditions of an Buehler test. [14]

- *Respiratory:* Data not available in the literature search carried out.

- Repeated dose toxicity (experimental.):

When tetramethrin (technical product, 93.3% purity) was fed daily to mice (dose levels of 0, 12, 60, 300, or 1500 mg/kg diet) for 104 weeks, there were no significant dose -related changes in survival, clinical signs, mean body weight, or food consumption. The NOEL was considered to be 12 mg/kg diet.[8].

In a 90 day oral toxicity study on rats with administration of 6000, 12000 or 24000 ppm Piperonyl Butoxide daily, toxicity of the substance in rats was directed primarily to the liver and kidney. LOAEL was 6000 ppm. [14]

In a repeated dose 90-Day oral toxicity study with Piperonyl Butoxide in non-rodents (dog), based on the lower body weight gain and signs of hepatotoxicity at 2000 and 3000 ppm, a NOAEL of 1000 ppm (equal to 14.8 mg/kg bw per day) was established. LOAEL is assumed to be 2000 ppm, equal to 63 mg/kg b.w./day (males) and 61 mg/kg bw/day (females). [14]

In a study on rats, the inhalation of active isothiazolones aerosols at concentrations of 0, 0.027, 0.23, 0.89 mg/m3 for 6 hours/day for 5 days/week for 13 weeks, caused, at the highest doses, reduced body growth in both sexes, reduction of serum proteins in females and the loss of weight of the spleen in males. Histopathology showed mild rhinitis at the dose of 0.23 mg/m3. [15]

- CMR effects:

- Germinal cell mutagenicity: Cypermethrin was not mutagenic in in vitro assays for gene mutation in bacteria and in V79 Chinese hamster cells, in a cytogenetics assay and in a sister chromatid exchange (SCE) assay in human lymphocytes. In vivo assays for mutagenicity gave conflicting results. The overwhelming evidence suggested that cypermethrin is not mutagenic. [1]

  Neither tetramethrin nor its 1R,cis/trans isomers were mutagenic in a variety of in vivo and in vitro test systems, which investigated gene mutations, DNA damage, DNA repair, and chromosomal effects. [9]

  Piperonyl Butoxide was not genotoxic in various in vitro and in vivo genotoxicity tudies. [14]

  Reaction mass of isothiazolones (CAS 55965-84-9) was mutagenic in Ames test. [15]

- Carcinogenicity: No increase in tumour incidence was observed in a 2-year study in rats fed dietary concentrations of cypermethrin equivalent to approximately 0, 0.05, 0.5, 5 or 50 mg/kg bw/day, The NOEL was 5 mg/kg bw/day, based on reduced bodyweight gain at the higher dose. [2].

  Tetramethrin meets the criteria for possible human carcinogen. When administered to Sprague-Dawley rats, it was associated with a significant dose-related increase in the incidence of interstitial cell adenomas in the testes in mid- and high-dose males. [11]

  In a 2-year combined chronic toxicity /carcinogenicity study with Piperonyl Butoxide (PBO) , no biologically significant toxicological changes occurred in rats receiving 30 mg/kg/day. The no observed adverse effect level (NOAEL) for PBO under the conditions of an OECD Guideline 451 carcinogenicity study on mice was considered to be 30mg/kg/day. [14]

- Reproductive toxicity: Cypermethrin was not teratogenic or foetotoxic in rats or rabbits at dose levels which caused maternal toxicity. Reduced litter size and weights were observed in a 3 - generation study in rats at dose levels which also caused reduced bodyweight gain in the parents. The NOEL was 5 mg/kg bw/day. [2]

  Tetramethrin (technical product) was orally administered (dose levels of 0, 100, 300, and 1000 mg/kg body weight per day) to rats from day 17 of gestation to day 21 of lactation (perinatal and postnatal period) and had no detectable effects on the survival rate of pups, growth and development, sensory function, motor function, learning ability, or reproductive ability. The NOEL was considered to be 100 mg/kg body weight per day for dams and >1000 mg/kg body weight per day for pups. [8]

  In a Prenatal Developmental Toxicity Study on rabbit, PBO elicited neither a fetotoxic nor a teratogenic effect at dosage levels of 200mg/kg/day or less when administered orally to female rabbits. No embryotoxicity or developmental toxicity including teratogenicity was observed in a Prenatal Developmental Toxicity Study on rat. [14]

  Reproduction and teratogenicity studies with rats, given isothiazolone doses of 1.4-14 mg/kg/day orally from day 6 to day 15 of gestation, showed no treatment related effects in either the dams or in the foetuses. [15]

- Specific Target Organ Toxicity (STOT)-single exposure:

Data not available in the literature search carried out.

- Specific Target Organ Toxicity (STOT)-repeated exposure:
Pyrethroids may cause adverse effects on the central nervous system. Long-term feeding studies have caused increased liver and kidney weights and adverse changes to liver tissues in test animals. (3)
Signs of central nervous system toxicity of Cypermethrin were observed in 3-month repeated dose studies in rats and dogs. The NOELs were 100 and 50 mg/kg feed, respectively, corresponding to 5 and 12.5 mg/kg bw/day. (2)
In a 28 day study on rats exposed to a respirable mist of tetramethrin, there were no compound-related effects on body weight gain, food and water consumption, urinalysis, haematology, biochemistry, organ weight, and histopathology. The NOEL in subacute inhalation was considered to be 49 mg/m3. (9)

- Aspiration hazards:
Data not available in the literature search carried out.

- Epidemiological information:
Data not available in the literature search carried out.

- Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Directives mentioned in this data sheet.

SECTION 12
ECOLOGICAL INFORMATION

12.1. Toxicity

Acute toxicity with fish	LC_{50} (*Salmo trutta m.lacustris*) = 0.002	mg/l/96h	for Cypermethrin	(7)
	LC_{50} *(Salmo gairdneri)* = 0.0005	mg/l/96h	for Cypermethrin	(7)
	LC_{50} (*Bracyidanio rerio*) = 0.033	mg/l/96h	for Tetramethrin	(13)
	LC_{50} (*Cyprinodon variegatus*) = 3.94	mg/l/96h	for Piperonyl butoxide	(14)
	LC_{50} fish = 0.19	mg/l/96h	for Reaction mass (CAS 55965-84-9)	(15)
Acute toxicity with *Daphnia magna*	LC_{50} = 0.002	mg/L/24h	for Cypermethrin	(7)
	EC_{50} = 0.47	mg/L/48h	for Tetramethrin	(13)
	EC_{50} = 510	µg/L/48h	for Piperonyl butoxide	(14)
	LC_{50} = 0.16	mg/L/48h	for Reaction mass (CAS 55965-84-9)	(15)
Acute toxicity with algae	IC_{50} (*Scenedesmus subspicatus)* = 1.36	mg/L/72h	for Tetramethrin	(13)
	ErC50 (*Selenastrum capricornutum)* = 3.89	mg/L/72h	for Piperonyl butoxide	(14)

12.2. Persistence and degradability

Cypermethrin has a very low vapor pressure and is not readily volatilized into the atmosphere. Experimental results indicate that there is practically no movement of the substance from contaminated soils to the surrounding air. It readily adsorbs to suspended matter in natural waters, and is therefore unlikely to cause groundwater contamination. (5)
Under normal environmental temperatures and pH, cypermethrin is relatively stable to hydrolysis and photolysis with the half-lives being >50 and >100 days, respectively (hydrolyzes slowly in water at pH 7 and below, with hydrolysis and photolysis more quickly in a basic environment.). In soil cypermethrin is degraded by hydrolysis of the ester linkage, leading to 3-phenoxybenzoic acid (PBA) and 3-(2,2-dichlorovinyl)-2,2-dimethyl cyclopropanecarboxylic acid (DCVA), with a small amount of 3-phenoxybenzaldehyde as a minor photoproduct. Cypermethrin is relatively non-persistent in soils with the typical half-life in sandy soils of 2-4 weeks. The persistence of the metabolites is unknown. Increased cypermethrin persistence was observed in soil with high organic matter, high clay content, reduced microbial activity and anaerobic conditions. Microbes play a significant role in the degradation of cypermethrin (degrades more slowly in sterilized versus natural soils, with a half-life of 20 to 25 weeks). The anaerobic half-life reported at <14 days is similar to the half-life in aerobic soils ranging from 6-20 days.
If released into the air, tetramethrin will exist in both the vapor and particulate phases in the atmosphere. The half -life of the vapor phase is three hours. If released into water, tetramethrin is expected to adsorb to suspended solids and sediment based upon the estimated Koc value of 790 (determined from a log Kow of 4.73). (8)

Volatilization from water surfaces is expected to be an important fate process. Tetramethrin is susceptible to alkaline hydrolysis.
In a biodegradation study, tetramethrin was mildly biodegradable. (13)
Methylisothiazolinone is very volatile. (15)
Piperonyl Butoxide is not readily biodegradable under aerobic conditions according to the criteria defined by OECD guideline 301 D. The substance is hydrolytically stable in solution in the dark at 25°C at pH 5,7,9 and its half-life under these conditions is greater than 500 days. 14C-Piperonyl Butoxide was not significantly degraded in the anaerobic aquatic metabolism study. Furthermore, the progressive accumulation of the test substance by the sediment could be observed. In soil samples, no significant residues of Piperonyl Butoxide were detected. It undergoes microbial and/or chemical degradation under aerobic soil conditions to eventually mineralize to CO2 (half-life: 10 days). The degradation rate is reduced when flooding occurs and anaerobic conditions are induced (half-life: 144 days). (14)

12.3. Bioaccumulative potential

Because of its high lipoaffinity and low solubility, cypermethrin has a strong potential to bioaccummulate in aquatic animals. (5)
A BCF of 420 in golden ide fish (Leuciscus idus melanotus and 430 in rainbow trout (Oncorhynchus mykiss), suggests the potential for bioconcentration of Cypermenthrin in aquatic organisms is high. (6)
An estimated BCF of 34 suggests the potential for Tetramethrin's bioconcentration in aquatic organisms is moderate, provided the compound is not metabolized by the organism. (8)
Related to Piperonyl Butoxide, bioconcentration factors obtained for edible tissue, whole fish, and nonedible tissue were 91, 260 and 380 respectively. (14)

12.4. Mobility in soil

Koc values ranging from 5,800 to 160,000, indicate that cypermethrin is expected to be immobile in soil. (6)
Very little cypermethrin insecticide would move through the soil profile, its major metabolites are very polar, and move readily through the soil. (5)
Koc values of 2045 and 2754 indicate that tetramethrin is immobile and remains mainly in the soil. (13)
Piperonyl Butoxide was moderately well adsorbed to the sandy loam, silt loam, clay loam soils and only weakly to sand. Based on the results, Piperonyl Butoxide can be classified as having a low to moderate potential for mobility in sandy loam, clay loam and silt loam and a high mobility in sand. (14)

12.5. Results of PBT e vPvB assessment

Data not available.

12.6. Other adverse effects

Cypermethrin is highly toxic to bees. (3)
Tetramethrin was found to be highly toxic to non-target bees, and practically non-toxic to birds and mammals. (12)

SECTION 13
DISPOSAL CONSIDERATION

13.1. Waste treatment methods

Any disposal practice must be in compliance with all local and national laws and regulations. Do not dump into any sewers, on the ground, or into any body of water.

SECTION 14
TRANSPORT INFORMATION

- ONU Number: **3082**
- UN proper shipping name: **ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (CONTAINS PYRETHRINS, PYPERONIL BUTOXIDE, CYPERMETHRIN)**

ADR **RID**

Class, Code, Group: 9 M6 III
Hazard identification number: 90
LQ: 5 L
Tunnel Restriction code: (E)

Class, Code, Group: 9 M6 III
Hazard identification number: 90
LQ: 5 L

IMDG

Class: 9
Packaging group: III
EmS sheet: F-A, S-F
Marine Pollutant: YES

IATA

Class: 9
Hazard Label(s): Miscellaneous
Packaging group: III
Erg code: 9L
Passenger and cargo: (LIMITED QUANTITY) P.I.: Y964;
max net q.ty per pack: 30 kg G;
Passenger and cargo: P.I.: 964; max net q.ty per pack: 450 L;
Cargo only: P.I.: 964; max net q.ty per pack: 450 L.

Transport in bulk according to Annex II of Marpol 73/78 and the IBC code: not applicable.

SECTION 15
REGULATORY INFORMATION

15.1 Safety, Health and Environmental regulation/legislation specific for the mixture or its ingredients

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

15.2. Chemical Safety Assessment

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 16
OTHER INFORMATION

Revisions:
- Edition dated 12/12/2011
- Revision n. 00

The classification of this product is based, where possible, on the data related to the mixture itself. Where no or inadequate test data on the mixture itself are available, the classification is

based upon other available information on individual substances and similar tested mixtures which may also be considered relevant for the purposes of determining whether the mixture is hazardous.

Bibliographic sources:

(1) IPCS INCHEM, DATA SHEET ON PESTICIDES No. 58 CYPERMETHRIN
(2) European Medicines Agency, CYPERMETHRIN (Extrapolation to all ruminants) SUMMARY REPORT (4), EMEA/MRL/890/03-FINAL June 2004
(3) EXTOXNET, Pesticide Information Profile, Cypermethrin, Publication Date: 9/93
(4) RTECS:GZ1250000 The Registry of Toxic Effects of Chemical Substances, CAS #: 52315-07-8
(5) ENVIRONMENTAL FATE OF CYPERMETHRIN, DeeAn Jones, Environmental Monitoring & Pest Management, Department of Pesticide Regulation Sacramento, CA 95814-3510
(6) CYPERMETHRIN - National Library of Medicine HSDB Database
(7) Data bank of environmental properties of chemicals, Cypermethrin
(8) TETRAMETHRIN - National Library of Medicine HSDB Database
(9) IPCS INCHEM INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY, ENVIRONMENTAL HEALTH CRITERIA 98, TETRAMETHRIN
(10) ChemID Lite Plus, Full record for Tetramethrin
(11) EPA Reregistration Eligibility Decision (RED) Document for Tetramethrin
(12) http://toxipedia.org/display/toxipedia/Tetramethrin
(13) ENDURA spa, TTMG CLP – Tetramethrin Technical Grade MSDS, revision date: 24/11/2010
(14) http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances , 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether
(15) http://www.salute.gov.it/sicurezzaChimica/paginaInternaMenuSicurezzaChimica, MSDS for Reaction mass off: 5-cloro-2-metil-2H-isotiazol-3-one [EC no 247-500- 2Hisotiazol-3-one [EC no 220-239-6] (3:1)
(16) ChemIDplus Lite, Kathon 886, Full record
(17) ChemIDplus Lite, Cypermethrin, Full record
(*) Classification in Annex I of Dir 67/548/EEC and in Annex VI of the 1272/2008/EC Regulation

Acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI : Biological Esposure Indices (Indici di esposizione biologica)
- CAS: Chemical Abstract Service (division of the American Chemical Society
- CHETAH : Computer programme for chemical termodynamics and energy release evaluation
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for re production substances
- EINECS: European Inventory of existing Commercial Substances
- EPA: US Environmental Protection Agency
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- N.A.: Not Applicable
- N.A.: Not Available
- NOAEL: No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE : Personal protective Equipment
- PBT: Persistent, Bioaccumulative and Toxic substances
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative

Information related to the regulation EC/1272/2008

List of hazards statements

H332	Harmful if inhaled.
H302	Harmful if swallowed.
H335	May cause respiratory irritation.

H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H331	Toxic if inhaled.
H311	Toxic in contact with skin.
H301	Toxic if swallowed.

List of precautionary statements

P102	Keep out of reach of children.
P273	Avoid release to the environment.
P280	Wear protective gloves.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national/ international regulation.

Information related to the Directive 67/548/EEC, Directive 1999/45/EC and Regulation (EC) n. 1907/2006

R20/22	Harmful by inhalation and if swallowed.
R37	Irritating to respiratory system.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R34	Causes burns
R43	May cause sensitization by skin contact.
R36/38	Irritating to eyes and skin.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S2	Keep out of the reach of children.
S24	Avoid contact with skin.
S28	After contact with skin, wash immediately with plenty of water.
S37	Wear suitable gloves.
S46	If swallowed, seek medical advice immediately and show this container or label.
S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Information on workers training
Follow criteria of Directive 98/24/EC, its amendments and National reinforcements.
Restriction of use (for ingredients): None.
Mixture which contains a substance under authorisation: **NO.**

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