	SAFETY DATA SHEET	
	TIMPEST ANTITARLO	Edition : 01 Revision: 00 Data: 23/10/2015

In accordance with Regulation (CE) N. 1907/2006 and subsequent modifications and supplements and Regulation (EC) N. 1272/2008

SECTION 1.
IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1. Mixture identifier

Mixture name:	**TIMPEST ANTITARLO**
Registration number:	01-2119457273-

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

Relevant use(s)	Woodworm
Uses advised against	Primer for wood protection

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier: Mario Mazzoni Eredi di Mauro Mazzoni & C.S.a.s.
Via Isonzo 28 - 34070 MOSSA - (GO)
Tel. + 39 0481 80487
Fax +39 0481 809866

E-mail address of the competent person responsible for the Safety Data Sheet: **info@timpest.com**

1.4. Emergency telephone number

Poison Center Milano: Tel. 0266101029 –
Poison Center Hospital Niguarda Cà Granda - (MI) (H24)
Poison Center Pavia: Tel. 0382 24444 - CAV IRCCs Maugeri Foundation (PV)
Poison Center Roma: Tel. 06 3054343 - CAV Polyclinic Gemelli (RM)
Poison Center: Tel.0817472870 - CAV Hospital Cardarelli (NA)
Poison Center: Tel. 010 56361 - CAV Hospital G. Gaslini (GE)

SECTION 2
HAZARDS IDENTIFICATION

2.1 Classification of the mixture

- **Classification of the mixture in accordance with Regulation (EC) n. 1272/2008:**

Hazard class	Class code and hazard category	Hazard statement	Hazard warning
Aspiration toxicity	**Asp. Tox. 1** **Note 4** **Note P**	**H304**	**H304** - May be fatal if swallowed and enters airways
Hazardous to the aquatic environment	**Aquatic Acute 1** **Aquatic Chronic 1**	**H400** **H410**	**H400 -** Very toxic to aquatic life **H410 -** Very toxic to aquatic life with long lasting effects

Main adverse effects
Physico-chemical effects: Not foreseen
Health effects May be fatal if swallowed and enters airways.
Environmental effects Very toxic to aquatic life with long lasting effects.
See also sections from 9 to 12

2.2 Label elements

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

Pictograms			
Signal Word	**Danger**	**Warning**	
Hazard Statements [*]	**H304**	**H400**	**H410**
Safety statements (P) [*]			
- *Prevention*	**P201 -** Obtain special instructions before use **P202 -** Do not handle until all safety precautions have been read and understood **P273 -** Avoid release to the environment **P281 -** Use personal protective equipment as required		
- *Response*	**P301+P310** - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. **P331** - Do NOT induce vomiting. **P391** – Collect spillage.		
- *Storage*	**P405 -** Store locked up.		
- *Disposal*	**P501**- Dispose of contents/container in accordance with local /regional /national/ international regulation		

[*]For the meaning of the hazard and Safety Advice: See Section 16

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

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

- Health hazards	Ingestion/Inhalation: may be fatal if swallowed and enters airways Contact with skin: may cause irritation to skin. Contact with eyes: may cause irritation to eyes.
- Environmental hazards	Very toxic to aquatic life with long lasting effects.
- Physico-chemical hazards	No smoking. The mixture emits toxic smoke in case of fire.
- Specific effects	Specific effects related to this mixture are not known.

SECTION 3
COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients:

Name	Number EC	Number CAS	Conc.% (p/p)	Classification (1272/2008/EC)[*]
Naphtha (petroleum), heavy "hydrotreating" (Registration number: 01-2119457273-39)	918-481-9	64742-48-9	99.68	Asp. Tox. 1, H304 Note 4 Note P
m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Permethrin)	258-067-9	52645-53-1	< 2	Acute Tox. 4, H302 Skin Sens. 1, H317 Acute Tox. 4, H332 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

[*]For the explanation of Hazard statements and Risk phrases: see Section 16

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 eyelids open with the finger. Get medical advice and show him the label.
- *Skin contact:*	Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and large amount of water until no evidence of mixture remains (15-20 minutes). Get medical immediately and show him the label.
- *Ingestion:*	If swallowed wash mouth with water provided person is conscious. Get medical immediately and show container or label.
- *Inhalation:*	Avoid breathing dust that may be generated by handling the product. Move to fresh air in a well-ventilated area. Consult your doctor if the exposure was significant in terms of quantity or time.

4.2 Most important symptoms and effects (acute and delayed)

- *Acute effects:*	Ingestion: strong abdominal and stomach pain. Inhalation exposure: strong irritation of the mucous membranes of the upper airways. Contact with skin: possible redness. Contact with eyes: possible burning sensation, redness of conjunctiva.
- *Delayed effects:*	Not foreseen.

4.3 Indication of any immediate medical attention and special treatment needed

- *Medical monitoring:* The competent doctor defines medical examinations to be carried out in order to protect the health of workers.
- *Antidotes, if known:* Unknown
- *Contraindications:* Unknown
- *Immediate treatment at workplace:* In the case of reactions described under "Hazard Indications" or other severe, immediate, or persistent reactions, call a physician or contact the nearest poison control center. Show product label and the present MSDS.

SECTION 5
FUREFIGHTING MEASURES

5.1 Extinguishing media

- *Suitable extinguishing media:* CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- *Unsuitable extinguishing media:* Water jet.

5.2 Special hazards arising from the mixture

- *Hazardous combustion products:* Smoke, Fume, products of incomplete combustion. Oxides of carbon.

5.3 Advice for firefighters

- *Technical actions for protection:* Don't try to extinguish the fire without an autonomous respiratory device (SCBA) and protective adapted clothes.
- *Special protective equipment for firefighters:* Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria 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

- *Eye:* Wear suitable protected devices. (see section 8)
- *Skin:* Wear suitable clothes with full body protection.
- *Inhalation:* In case of fire and/or explosions avoid to breathe smokes and vapours. Use a respiratory device autonomous (SCBA) and adapted protective clothes. The vapours can be eliminated through nebulized with water.

- For emergency responders

- *Eye:* see section 8
- *Skin:* see section 8
- *Inhalation:* see section 8

6.2 Environmental precautions

In case of accidental release in the environment avoid that the mixture can reach drains, surface water and ground water.

6.3 Methods and material for containment and cleaning up

- *Containment procedures:* Collect all of the material scattered on the ground with protective equipment adapted.
- *Cleaning up procedures:* Recover the mixture for suction or with other mechanic means and wash the area with plenty of water and cleanings. Store the recovered product recovered in wait of the skilled disposal society. If the effusion happened in highway or in a public

place, suitable trickiness should be adopted in order to protect the 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

- *Recommandations for handling:*	Handle away from sparkles and flames - sources of ignition Handle in a well ventilated place Avoid contact with incompatible materials Wear suitable Personal Protection Equipment (see section 8) Keep the mixture away from drains, surface or ground waters
- *Recommandations 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 :
- *Potential ignition sources:* Don't expose to heat sources.

Procedure to control other effects
- *Weather conditions:* It is not expected any procedure of restriction.
- *Ambient pressure:* It is not expected any procedure of restriction.
- *Temperature:* Store at room temperature (+15°C – +25°C).
- *Sunlight:* Don't expose to the direct light of the sun.
- *Humidity* Don't store in a damp place.
- *Vibration:* It is not expected any procedure of restriction.

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.

Material to keep the integrity of the mixture
- *Stabilisers:* Use of stabilisers is not expected
- *Antioxidants:* Use of antioxidants is not expected

Other advice
- *Ventilation requirements* Requested on the base of the storage of the mixture
- *Specific design of storage rooms* Not requested on the base of the classification
- *Quantity limits for storage* Not requested on the base 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 present in databases consulted
- Non European Occupational Exposure Limits	*Naphtha (petroleum), heavy "hydrotreating"*: TLV – TWA (8h): 1200 mg/m^3 (148 ppm).[2]
- National/ European Biological Limits (BEI):	Not present in databases consulted
- Other National/ European Biological Limits (BEI):	Not present in databases consulted
- Recommended monitoring procedures	The measurement of substances in the workplace should be performed with standardized methods (*eg* UNI EN 689:1997: Atmosphere at work - Guidance on assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy, UNI EN 482:2006: atmospheres in the workplace - General requirements for performance of procedures for the measurement of chemical agents) or, in their absence, with appropriate methods.
- DNEL values (components)	Chemical Safety Report has not been performed
- PNEC values (components)	Chemical Safety Report has not been performed

8.2. Exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X
- Accordance with the controlled conditions of use Only for intermediate registered under art. 17 to 18		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 described in the Reach registration Dossier is not available.

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.
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
b) Skin protection	
- *Hands protection*	Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/EEC. The gloves material must be waterproof and stable against the mixture content. Select the glove material on the basis of the type of the material, typical or minimal breakdown times, permeability ranges, thickness. Material: nitrile (nitrilic rubber), ipoallergenic Thickness: not inferior to 0.12 mm
- *Other, body protection*	Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 14605 in case of sketches.
c) Respiratory protection	When the risk evaluation foresees the need to use respirator devices with assisted

	ventilation, use a powder filter like P1, P2 and P3. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU). In case of brief exposure or low pollution use respiratory filter In case of deeper and longer exposures use self-contained breathing.
d) Thermal hazards	Not foreseen in the standard use. Assess possible Personal Protection Equipment on the basis of specific uses of the mixture.

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:	Clear liquid
Odor:	Characteristic
Odour threshold:	Not found after bibliographic research.
pH:	Not found after bibliographic research.
Melting point/freezing point:	-20°C [1]
Initial boiling point:	160°C [1]
Flash point:	> 61 °C [1]
Evaporation rate:	Not found after bibliographic research.
Flammability (solids, gas):	Not found after bibliographic research.
Upper/lower flammability or explosive limits	Not found after bibliographic research.
Vapour pressure:	Not found after bibliographic research
Vapour tension:	1 hPa at 20°C.[1]
Density:	0.751 g/cm³ at 20°C.[1]
Water solubility:	0.04 g/l.[1]
Solubility in organic solvents:	Not found after bibliographic research
Partition coefficient Octanol/water (Log Kow):	Not found after bibliographic research
Autoignition temperature:	260 °C.[2]
Autoignition:	Product is not self-igniting.[1]
Decomposition temperature:	Not found after bibliographic research.
Viscosity:	Kinematic: 2.067 cSt at 20°C and 1.534 cSt at 40°C.[2] Dymanic: 1.635 mPa*s at 20°C and 1.203 mPa*s at 40°C.[2]
Explosive properties:	Not found after bibliographic research.
Oxidising properties:	Not found after bibliographic research.

9.2. Other information

Fat solubility:	Not found after bibliographic research
Conductivity:	Not found after bibliographic research
Henry's Law Constant:	Not found after bibliographic research

SECTION 10
STABILITY AND REACTIVITY

10.1. Reactivity

This mixture is considered not reactive under the normal conditions of the usage. Reacts on contact with strong oxidizing agents.

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	-	

10.3. Possibility of hazardous reactions

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

10.4. Condition to avoid

Avoid exposure to light, air, moisture and excessive heat.

10.5. Incompatible materials

Strong oxidant agents.

10.6. hazardous decomposition products

Thermal decomposition and combustion may produce toxic fumes containing COx and other substances in case of incomplete decomposition.

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:	Strong abdominal and stomach pain.
-Inhalation:	Strong irritation of the upper airway mucosa.
-Skin contact:	Possible redness.
-Eye contact:	Possible burning sensation, redness of conjunctiva.

- Toxico-kinetics information (ADME = Adsorption, **D**istribution, **M**etabolism, **E**xcretion**):**

Permethrin

Following an oral absorption study Permethrin was found to undergo rapid and extensive absorption in the body. According to Gaughan & Casida, 1977, residues levels recorded in the fat, liver and kidney were generally low and there was no evidence for accumulation. However, the *cis* isomer showed relatively higher residue levels (0.46-0.62 mg/kg tissue) in the fat. Major metabolites identified are Cl_2CA in free and glucuronide form, sulfate conjugate of 4'-hydroxy-3-phenoxybenzoic acid, PB acid in free and conjugate form, and hydroxymethyl-Cl_2CA as a glucuronide conjugate. Absorption and metabolism of permethrin is rapid and extensive, with only between 3 and 6% of the administered dose being recovered un-metabolised in faeces. Consequently, oral absorption is assumed to be 100%. Absorption via the inhalation route was also set to 100%. Inhalation absorption was assumed to be 100%.[4]

Dermal penetration

Dermal absorption has been set a 3% derived in a human dermal penetration study. The first two volunteers have been excluded from the derivation as they have a very low recovery and were regarded as outlines compared to the other 4 volunteers. In addition, the values have been normalised to 100% to compensate for the low recovery allowing

derivation of a dermal absorption value of 3% as a rounded figure.[4]

- Acute Toxicity:

- *Oral:*

On the basis of the resulted obtained from an Acute Oral Toxicity assay, test item TIMPEST ANTITARLO has a LD50 > 2000 mg/kg bw and can be included in class 5/NC of GHS classification.[2]
Naphtha (petroleum), heavy "hydrotreating"
LD50 (rat): > 5000 mg/kg.[1]

Permethrin
LD50 (rat): 1479 mg/kg.[1]

The acute oral studies submitted had LD50 values ranging from 480 - 1623 mg/kg bw/day. Therefore, Permethrin classifies as Xn: R22/H302; Harmful if swallowed.
Permethrin did not classify as toxic or harmful by the dermal route. Although the inhalation studies submitted by the current applicants indicated the substance did not require classification for inhalation, Permethrin is currently classified under Directive 67/548 as Xn: R20; Harmful by inhalation, and Regulation (EC) No. 1727/2008 as H332: Harmful if inhaled. This classification is based on a study (Brammer A., 1989) referenced in PPP DAR. Combining information in the PPP DAR and biocides CAR the following studies are available; one non-guideline negative study; one guideline positive study; one guideline negative study and an existing classification. The rationale of the RMS was is apply the precautionary principal and retain the classification based on the aforementioned data.[4]

- *Dermal:*

Permethrin
LD50 (rabbit): >4000 mg/kg.[1]

- *Inhalation:*

Naphtha (petroleum), heavy "hydrotreating"
LC50/4h (rat): > 4951 mg/m^3.[1]

Permethrin
LC50/4 h (rat): > 23.5 mg/l.[1]

Naphtha (petroleum), heavy "hydrotreating"
Five male and five female rats were exposed to an average nominal (gravimetric) concentration of 7630 +/- 900 mg/m³ and an average actual (measured by Miran) vapor concentration of 5610 +/- 300 mg/m³ of test article F-101 for four consecutive hours. No in-life observation effects were observed during the 14 day observation period. At necropsy, three of the five male rats had lung lesions that may be test article related. None of the animals died during the 14 day observation period. Based on the parameters of this study, the inhalation LC50 of test article F-101 is greater than an average nominal (gravimetric) concentration of 7630 +/- 900 mg/m³ and an average actual (calculated by Miran) concentration of 5610 +/- 300 mg/m³. These findings do not warrant classification of the test article as an acute inhalation toxicant under the new Regulation (EC) 1272/2008 on classification, labeling, and packaging of substances and mixtures (CLP) or under the Directive 67/518/EEC for dangerous substances and Directive 1999/45/EC for preparations.[3]

- Corrosion/Irritation effects:

Negative to an *in vitro* Skin Irritation Test. Therefore TIMPEST ANTITARLO must be considered not irritant for the skin.[2]
In predisposed individuals may cause mild irritation.

- Severe ocular lesion:

TIMPEST ANTITARLO is not irritating to an *in vitro* Eye Irritancy Assay (BCOP). Therefore is classified into UN GHS No Category. [2]

- Sensitisation:

- *Dermal:*

Permethrin
The study submitted by applicant 1, Parcell (1991) was negative for skin sensitisation. However, two previously evaluated studies (Leah, 1989 & Thakkar, Bharat 1995) both recorded positive results for permenthrin. According to applicant 2, Permethrin is not a skin sensitiser and does not require classification. However, the Buehler method, which was used in Applicant 2 study, is not recommended for

testing the active substance.
Under Directives 67/548 and 91/414 and Regulation (EC) No. 1727/2008, Permethrin is classified as a skin sensitiser, therefore the RMS proposed to retain the classification Xn: R43; May cause sensitisation by skin contact and H317; May cause an allergic skin sensitisation.[4]

- *Respiratory:* Not found after bibliographic research.

- Repeated dose toxicity (experimental.):

Permethrin

Permethrin is of relatively low repeat dose toxicity with effects seen at sub-lethal doses being mainly transient and reversible in nature. The critical effect in rats includes increased absolute and relative liver weight, the target organ. The liver weights were associated with hepatocellular hypertrophy. Via the oral route the 90 day rat studies from both applicants yielded NOAELs of about 175 mg/kg bw/day based on reversible liver effects. The combined overall relevant dermal LOAEL and NOAEL was 2000 and 1000 mg/kg bw/day, respectively, based effects including, tremors, piloerection, statistically significant decrease in bodyweight and food consumption and increased mean relative liver weights in males. Nasal irritation and mild tremor were noted following inhalation exposure with LOAEL and NOAEL 117.8 and 59.43 mg/kg bw/d, respectively.[4]

The dog was the most sensitive species. A NOAEL of 10 mg/kg bw/day was established in a 6-month dog study based particularly on increased liver weight at 50 and 250 mg/kg/day. An acute NOAEL of 250 mg/kg/day is based on clinical signs, mortality, bodyweight, ophthalmoscopy, electrocardiography. A NOAEL of 5 mg/kg bw/day has been established in a one-year dog study for permethrin (32% *cis*/60% *trans*) on the basis of histopathological changes in the adrenals in males and females, reduced bodyweight gain in females and increased liver weight in both sexes, accompanied by hepatic cellular swelling at 100 mg/kg bw per day.[4]

- CMR effects:

- Germinal cell mutagenicity: *Naphtha (petroleum), heavy "hydrotreating"*
API 84-02 (heavy thermal cracked naphtha) was examined for its potential to induce mutations in the L5178Y mouse lymphoma cell line, in both the presence and absence of an S9 metabolic activation system. The doses were of concentrations from 12.5 to 100 nl/ml without activation and 25 to 125 nl/ml with activation. API 84-02 induced a statistically significant increase in the number of mutant colonies at the highest dose level without activation and a dose-related increase with activation. Both the positive and negative controls responded appropriately. Under the conditions of this study, API 84-02 was mutagenic in mammalian cells in the presence and absence of metabolic activation. This finding alone does not warrant the classification of heavy thermal cracked naphtha as a genotoxin under the new Regulation (EC) 1272/2008 on classification, labeling, and packaging of substances and mixtures (CLP) or under the Directive 67/518/EEC for dangerous substances and Directive 1999/45/EC for preparations.[3]

The in vitro forward mutation assay in mammalian cells to assess the genotoxicity of heavy catalytically cracked naphtha (API 83-18) was positive. This finding alone does not warrant the classification of heavy catalytically cracked naphtha as a genotoxin under the new Regulation (EC) 1272/2008 on classification, labeling, and packaging of substances and mixtures (CLP) or under the Directive 67/518/EEC for dangerous substances and Directive 1999/45/EC for preparations.[3]

Baseline gasoline vapor condensate was examined for its potential to induce chromosomal damage in rat bone marrow erythrocytes from rats dosed via inhalation with the test material at 2000, 10 000, or 20 000 mg/m^3 for 6 hours per day, 5 days a week for a duration of 4 weeks. Vehicle control animals were dosed with clean air alone, and positive control animals were dosed intraperitoneally with 40 mg/kg dose of cyclophosphamide in sterile water. Bone marrow was collected from 10 animals (5/sex) from each treatment and control group at 24 hours after the final administration. No statistically significant increases in the frequency of micronucleated immature erythrocytes and no substantial decrease in the proportion of immature eyrthrocytes were observed in the dose groups treated with the test material compared to the negative control values (p>0.01 in each case). The positive control material caused both large, significant increases in the frequency of micronucleated immature erythrocytes and statistically significant decreases in the proportion of immature erythrocytes (p<0.001 in each case). Baseline gasoline vapor

condensate was considered to be non-genotoxic and non-clastogenic under the conditions of this test. This finding does not warrant the classification of baseline gasoline vapor condensate as a genotoxin under the new Regulation (EC) 1272/2008 on classification, labeling, and packaging of substances and mixtures (CLP) or under the Directive 67/518/EEC for dangerous substances and Directive 1999/45/EC for preparations.[3]

Permethrin

Permethrin was tested in a battery of *in vitro* and *in vivo* assays measuring several endpoints of potential genotoxicity such as gene mutation and chromosomal aberration.

The *in vitro* tests included four bacterial reverse mutation assays, three mammalian gene mutation tests, a UDS assay and a mammalian chromosome aberration assay. *In vivo* tests included two mammalian bone marrow chromosome aberration tests, a mammalian erythrocyte micro-nucleus test and a Rodent dominant lethal test. Permethrin did not exhibit genotoxic potential in the standard set of tests. However, in one of the chromosome aberration assays (Barrueco et al 1994) as positive result in the absence of S9 was recorded. However this study was not conducted under GLP conditions and the protocol did not conform to the OECD guidance. In addition, two reliable and positive comet assays were submitted by the company. However, lack of guidance on interpretation of comet assays, lack of a OECD guideline, lack a validated protocol and lack of GLP make the import of these tests difficult to quantify. Adopting the weight of evidence approach, factoring in the difficulties associated with comet assays, the conduct and lack of corroborating evidence for the findings of the Barrueco study, the three negative *in vivo* studies and the lack of a genotoxic profile for pyrethroids the RMS has concluded that permethrin is not genotoxic.[4]

- Carcinogenicity:

Naphtha (petroleum), heavy "hydrotreating"

Unleaded gasoline was examined for its carcinogenic potential. Unleaded gasoline was administered via dermal application to the skin of 50 Swiss mice three times per week for two years. A negative control group was not treated while the two positive control groups were administered 0.05 ml of 0.05% BaP and 0.05 ml of 0.15% BaP in acetone. The test substance caused hyperkeratosis, fibrosis of the dermis, extoabscess and skin ulceration in the treatment areas. The incidence of skin carcinomas, liver hemangiomas, lung adenomas, and malignant lymphomas was no greater with the test substance than for the negative control group. Unleaded gasoline was did not display carcinogenic properties in this study. This finding does not warrant the classification of unleaded gasoline as a carcinogen under the new Regulation (EC) 1272/2008 on classification, labeling, and packaging of substances and mixtures (CLP) or under the Directive 67/518/EEC for dangerous substances and Directive 1999/45/EC for preparations.[3]

Permethrin

Carcinogenicity and long term toxicity of permethrin have been investigated in the rat and the mouse. No treatment related change was seen in the incidence of tumours in either species. In chronic toxicity studies, NOAELs of 50 mg/kg bw/day (McSheehy & Finn, 1980) and 50 mg/kg bw/day (Ishmael & Litchfield, 1988) have been established in the rat for permethrin (25% *cis*/75% *trans*) and permethrin (40% *cis*/60% *trans*) respectively, whilst a NOAEL of 150 mg/kg bw/day has been established for permethrin (40% *cis*/60% *trans*) in the mouse (Ishmael & Litchfield, 1988).

A NOAEL of 75 mg/kg derived in the Baskaran, J. (2007) study with no evidence of carcinogenicity these findings were in line with the other chronic rat and mouse studies.[4]

- Reproductive toxicity:

Naphtha (petroleum), heavy "hydrotreating"

The generational reproductive study was conducted at levels up to 20000 mg/m3, approximately half of the lower explosive limit, and the highest level considered safe for use in the laboratory. VRU gasoline did not produce any pathologic changes in reproductive organs. Additionally, there were no differences in mating, fertility,

live births, birth weights, and survival or weight gain through weaning. Finally, there were no differences in sperm count, sperm quality, estrous cycling, quantification of primordial oocytes, or developmental landmarks, other than a delay in hair growth in some treated offspring.
There were weight and histopathological changes noted in the kidneys of the high-dose (20000 mg/m3) exposed males from the second parental generation, as well as microscopic evidence of hyaline droplets in the male rat kidneys from both generations. However, as the weight difference was slight (<6%), found only in one generation, and seen only in the males, it was not considered to be adverse. The microscopic changes were consistent with an alpha-2u globulin-mediated process that is unique to male rats and not toxicologically relevant to humans.
Based on the data reported, the reproductive NOAEL as defined by this study is >20000 mg/m^3.[3]

Unleaded gasoline vapor condensate was administered once daily to pregnant rats on gestation days 6-19 via vapor inhalation at doses of 0, 2653, 7960, or 23900 mg/m3 (24 rats/dose) to assess for developmental toxicity. Maternal parameters (food consumption, body weight gain) monitored throughout gestation and at study termination (clinical chemistry, grossly visible abnormalities) were not adversely affected by treatment. Reproductive parameters (number of implants, resorptions, or viable fetuses) were not adversely affected by administration of the test material at any of the dose levels tested. No evidence of abnormal development was observed during external, skeletal, or visceral examinations of fetuses from pregnant dams exposed. Thus, unleaded gasoline vapor condensate did not produce any maternal toxicity, fetal toxicity, or developmental effects in rats. Based on the study results, the maternal and developmental NOAELs were both 23900 mg/m3. These findings do not warrant the classification of the test material as a developmental hazard under the new Regulation (EC) 1272/2008 on classification, labeling, and packaging of substances and mixtures (CLP) or under the Directive 67/518/EEC for dangerous substances and Directive 1999/45/EC for preparations.[3]

Permethrin
Reproductive performance was unaffected in both sets of data submitted. The RMS deemed the 2-generation study submitted by applicant 1 (Bayer) as the most appropriate for determining the overall relevant reproductive NOAEL and LOAEL. James, 1979, observed that following exposure of rats to Permethrin during their reproductive life did not cause significant treatment related maternal or pup effects up to and including 180-mg/kg bw/day. Based on the findings observed under the conditions of this study, the dose of 180mg/kg bw/day was established as the parental and reproductive toxicity NOAEL. Therefore the NOAEL for parental and fertility effects were 180 mg/kg bw/day.
Permethrin exposure to rabbits in utero was not teratogenic. Litters exposed to the high dose of Permethrin (400 mg/kg bw/day) did not exhibit a treatment or dose related effect on external malformations, visceral or skeletal abnormalities. On the basis of these results, the dose level of 400-mg/kg bw/day was considered to be No Observed Adverse Effect Level (NOAEL) of the study for foetal effects.[4]

No data on carcinogenicity are available on this mixture on the following data bases EPA, NTP, OSHA o ACGIH

- Specific Target Organ Toxicity (STOT)-single exposure:
Not found after bibliographic research

- Specific Target Organ Toxicity (STOT)- repeated exposure :
Not found after bibliographic research

- Aspiration hazards:
Under normal conditions of use present no dangers.

- **Neurotoxicity:**
Permethrin
Permethrin has no delayed neurotoxic potential such as that associated with certain organophosphates (Bond *et al*,

1980), however, there is evidence that motor activity and acetylcholine receptors in mice can be negatively impacted by repeated inhalation exposure to permethrin (25% cis/75% trans). Increased rearing activity in male mice and a reduction in muscarinic receptors in the brains of male and female mice was associated with inhalation treatment with permethrin. However, derivation of a NOAEL from the inhalation study appears almost impossible. The study was a whole body exposure study of pups and dams and does not have a pharmacokinetic testing element.
Therefore, the amount of exposure via ingestion, inhalation or dermal absorption cannot be quantified. Also, the study was non-guideline, non-GLP for research purposes. In the context of this type of exposure it is very difficult know what the dose actually was and consequently to derive a systemic NOAEL.[4]

It is proposed that a study to investigate the neurotoxic potential of exposure to Permethrin is not required, as there is sufficient data available in the open literature and the mechanism of action is well documented. Rats were administered Permethrin (cis:trans ratio: 36%: 59%, purity 95.3%) at doses of 0, 10, 150 and 300 mg/kg bw. Clinical signs such as tremors, staggered gait and effects on hind limb were noted at 300 mg/kg bw. Neuropathological examination of nervous tissue revealed no treatmentrelated lesions. The NOAEL was considered to be 150 mg/kg bw (JMPR, 1999).
Permethrin (cis:trans ratio: 36%: 59%; purity: 95.3%) was administered in the diet to rats for 28 days, at concentrations of 0, 100, 750, 1500, 3000, 4000 or 5000 ppm. Treatment related clinical signs; similar to those observed in the previous study, were seen at doses >= 1500 ppm. The NOAEL was therefore considered to be 750 ppm (38 mg/kg bw/day). Rats were administered Permethrin for 90 days (cis:trans ratio,36%:59%; purity, 95.3%) at concentrations of 0, 250, 1500 and 2500 ppm in the diet. Clinical signs such as staggered gait, splayed hind limbs and tremors were reported at 1500 ppm. The NOAEL was 250 ppm (15 mg/kg/day). The aforementioned NOAEL values are all higher than the proposed AEL values for exposure.[4]

- Human data:
Permethrin
Toxicological evaluations on Permethrin have previously been carried out by the World Health Organisation (1990) and the JMPR (1999). For both evaluations observational data in humans was submitted. In WHO trials in Nigeria, no adverse effects were observed following indoor use of Permethrin at a rate of 0.5 g/m3. In a separate study summarised in the JMPR toxicological evaluation (1999) 23 laboratory workers involved in field trials, formulation or general laboratory work with synthetic pyrethroids (Cypermethrin, Permethrin, Fenvalerate and Fenpropathrin) were examined. No symptoms related to Permethrin were noted. All the workers were examined neurologically and no abnormal findings were recorded.[4]

Toxicological evaluations on Permethrin have previously been carried out by the World Health Organisation (1990) and the JMPR (1999). For both evaluations observational data in humans was submitted. In one report soldiers wore clothing impregnated with 0.2% w/v Permethrin (25:75) after which no adverse effects or signs of irritation were noted. Another, whereby a group of patients was treated for pediculosis capitis with a 1% Permethrin cream rinse. Cutaneous side effects such as pruritus and mild burning/stinging sensations were noted but as the preparation contained isopropanol (20%), a known skin irritant, a direct link to Permethrin was not established. Please refer to IIIA, 6.12.2 for further details. It can be concluded that Permethrin does not cause any adverse effects even when it is directly applied to the skin of humans. This submission relates to the use of Permethrin as a wood preservative and not for direct application to skin. However, this data is included here as it provides relevant information on the irritating effects of Permethrin, should it come in contact with human skin.[4]

- Reasons for the lack of classification:
Where the mixture resulted non classified, 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

Fish
Acute
LC50 *Brachydanio rerio* (96h): 44.105 mg/l.[2]

Aquatic invertebrates
Acute
EC50 (daphnies-48h): 0.286 mg/l.[2]

Algae and aquatic plants
Acute
Algae growth Inhibition test (72h): 7.64% at 100 mg/.[2]

Permethrin
The most critical long-term aquatic endpoint was the reproductive NOEC of 0.0000047 mg a.s./L on Daphnia magna, which is less than 0.01 mg/l trigger.
Permethrin (25:75) is considered to fulfil the T criteria.[4]

12.2. Persistence and degradability

TIMPEST ANTITARLO should be considered biodegradable in aerobic condition.[2]

Permethrin
Permethrin as the isomeric mixture 25:75 *cis*:*trans* is not persistent in aquatic systems, on the basis that its whole system DT chironomid (12 ºC) values do not fulfil the P criterion for sediment. However, a constituent of permethrin (the *cis isomer)* may have the potential to be persistent. Permethrin (25:75) is not considered to fulfil the P or vP criteria.[4]

12.3. Bioaccumulative potential

Permethrin
The reported Log Pow values for permethrin range from 4.6 to 6.1, indicating it is a fatsoluble molecule with a potential to bioconcentrate. However, experimentally derived BCF values for fish and chironomid ranged from 290 to 620 l/kg. Additionally, these data also indicated that residues were readily eliminated through depuration with approximately 80% of the residues depurated within 14 days. Permethrin (25:75) is not considered to fulfil the B or vB criteria.[4]

12.4. Mobility in soil

Not found after bibliographic research.

12.5. Results of PBT e vPvB assessment

On the base of the available information the mixture does not satisfy the criteria in order to be considered a PBT or vPvB.

Permethrin (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers.

Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the *cis* isomer) and therefore fulfill the P criteria.[4]

12.6. Other adverse effects

Not found after bibliographic research

- Reasons for the lack of classification:
Where the mixture resulted non classified, 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 13
DISPOSAL CONSIDERATION

13.1. Waste treatment methods

	Incineration	Recycling	Landfilling
- Mixture wastes:	X		
- Contaminated packaging:	X		

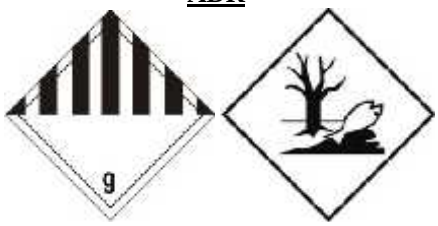
Sewage disposal is not allowed.

Refers to Community/National/Local requirements concerning the waste disposal.

SECTION 14
TRANSPORT INFORMATION

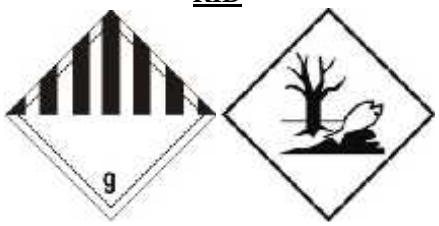
- UN Number: 3082
- UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Permethrin)

ADR



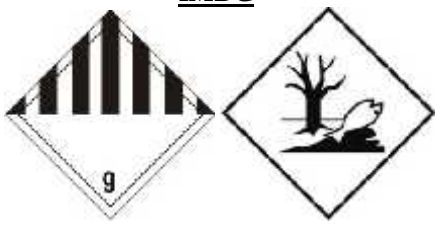
Class, Code, Group: 9 M6 III
Hazard identification number: 90
Limited quantities (LQ): 5 L
Tunnel Restriction code: (E)

RID



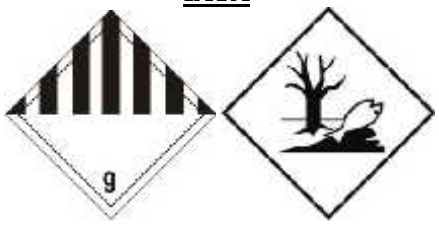
Class, Code, Group: 9 M6 III
Hazard identification number: 90
Limited quantities (LQ): 5 L

IMDG



Class: 9
Packaging group: III
Limited quantities (LQ): 5 L
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.
Special provisions: A97, A158.

SECTION 15
REGULATORY INFORMATION

All other information on regulation are reported if not provided in other sections/subsection of the Safety Data Sheet.

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

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

15.2. Chemical Safety Assessment

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

SECTION 16
OTHER INFORMATION

Revisions:
- **Edition n. 01 dated 23/10/2015 ((First Edition in accordance with Regulation (CE) N. 1907/2006 and subsequent modifications and supplements and Regulation (CE) N. 1272/2008)**
- **Revision n. 00**

Bibliographic sources:
[1] MSDS Mario Mazzoni Eredi di Mauro Mazzoni & C.S.a.s. TIMPEST ANTITARLO
[2] Internal data Mario Mazzoni Eredi di Mauro Mazzoni & C.S.a.s.
[3] Echa website
[4] Permethrin PT18 Assessment report. Rapporteur: Ireland. April 2014
Data Bank ChemSpider [http://www.chemspider.com/Search.aspx]
Data Bank ChemIDplus Lite [http://chem.sis.nlm.nih.gov]
pubchem.ncbi.nlm.nih.gov
stneasy.fiz-karlsruhe.de

Information relating to health, safety, and environmental protection in accordance with Regulation (EC) No 1272/2008

List of hazards statements

H304	May be fatal if swallowed and enters airways
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

List of P statements

Prevention	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P273	Avoid release to the environment.
P281	Use personal protective equipment as required.
Reaction	
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P331	Do NOT induce vomiting.
P391	Collect spillage.
Storage	
P405	Store locked up.
Disposal	
P501	Dispose of contents/container in accordance to local/regional/national/international rules.

Acronyms:
- ACGIH: American Conference of Governmental Industrial Hygienists
- ADI: Admissible Daily Intake
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI : Biological Esposure Indices
- CAS: Chemical Abstract Service (division of the American Chemical Society)

- 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
- NOEL: No Observed 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 on workers training
Follow criteria of Directive 98/24/EC, its amendments and National reinforcements
Restriction of use : None
Mixture under authorisation : No

DISCLAIMER

This document aims to provide guidance for appropriate handling of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless they are given adequate written information received on how to handle the material.
The provider of this document cannot provide any warnings related to the dangers of using, interaction with other materials or chemicals or user's safe use of the product, the suitability of the product for which is applied or its proper disposal. The information should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Annex II of Regulation (CE) N. 1907/2006 and subsequent modifications and supplements.