

	SAFETY DATA SHEET prepared in accordance with Article 31 of Regulation (EC) 1907/2006 (REACH) and Regulation (EU) 2015/830			
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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade name:

KICK THE TICK ® EXPERT

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

1.2.1. Relevant identified uses

Medical device for safe remove of skin adhered ticks.

1.2.2. Uses advised against

None

1.3. Details of the supplier of the safety data sheet

ICB Pharma Tomasz Świętosławski, Paweł Świętosławski Spółka Jawna

Address: Moździerzowców 6a, 43-602 Jaworzno, Poland

Phone: +48 32 745 47 00

e-mail: office@icbpharma.com

Person responsible for SDS: e-mail: grzegorz.zmijowski@icbpharma.com

1.4. Emergency telephone number:

112 – emergency number

+48 32 745 47 00 (at working hours: 8.00 a.m. – 4 p.m.)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

According to the Regulation (WE) no 1272/2008:

Aerosol, category 3 with assigned H phrase:

H229: Pressurised container: May burst if heated

Health hazard: none

Environmental Hazards: none

Physical/chemical hazards: aerosol, pressurised container

Fire hazard: none, product does not contain any combustible ingredients.

2.2. Label elements

According to the Regulation (WE) 1272/2008:

Pictogram:

Not applicable

Signal Word:

Not applicable

Hazard statements:

WARNING

Hazard Statement:

H229 Pressurised container: May burst if heated

Precautionary statement:

General:

P102 Keep out of reach of children.

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Prevention:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251 Do not pierce or burn, even after use.

Response:

Not applicable

Storage and disposal:

P410 Protect from sunlight.

2.3. Other hazards

The mixture doesn't meet the criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Product is a mixture fulfilling definition of medical device.

Chemical name	CAS No/ EC No	Index No	Content	Hazard class and hazard statement
1,1,1,2-Tetrafluoroethane	CAS: 811-97-2 WE: 212-377-0	Not applied	95 % w/w	Press. Gas, H280

For the wording of the listed risk category and hazard phrases refer to section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General recommendations: In the event of health problems, immediately contact doctor. In case of contact with the company emergency number or Poison Control Centre, person should have a product container, label or this MSDS. Never give anything by mouth to an unconscious person.

Contamination of the skin: Product is not irritant to skin.

Contamination of the eyes: Flush contaminated eyes with wide-open eyelids a continuous stream of water for about 10 minutes. In the case of persistent irritation consult an ophthalmologist.

Inhalation: Remove the victim from area of exposure, if breathing is difficult provide fresh air or oxygen. Get medical attention if necessary.

Ingestion: Rinse mouth immediately with water, if feeling unwell get medical help.

Protection of first aid responders

Do not take any action that would create a risk to the rescuer unless risk is now and suitable training is provided. First aider should avoid prolonged contact with the product without appropriate personal protection measures (see Section 8).

4.2. Most important symptoms and effects, both acute and delayed

Acute symptoms – no data

Delayed symptoms – no data

Effects of exposure – no data

4.3. Indication of any immediate medical attention and special treatment needed

Note to Physician: No specific antidote, treat symptomatically.

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SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: for small fires use CO₂, powder and foam extinguishers. For large fires use foam and water mist.

Unsuitable extinguishing media: not known.

5.2. Special hazards arising from the substance or mixture

Pressurised containers, high temperature might cause an explosion. Product chemical ingredients are not combustible. Combustion products might contain gases hazardous to health.

5.3. Advice for fire-fighters

Strictly apply the breathing apparatus and protective clothing for firefighting or during clean-up work immediately after a fire in an enclosed, or poorly ventilated areas.

General: Remove from the endangered area unauthorized persons, not involved in extinguishing the fire, order evacuation if necessary.

Additional notes: Packaging which are not covered by the fire, exposed to fire or high temperature should be cooled by water from a safe distance (explosion risk) and if possible removed from the hazardous area. Fire residues and contaminated extinguishing agents dispose according to applicable regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with releasing product, protect eyes. Use recommended personal protection measures. In case of release of large amounts of carrier gas close rooms should be well ventilated.

6.2. Environmental precautions

The product form and chemical composition does not pose any hazard to the environment.

6.3. Methods and material for containment and cleaning up

In case of container leakage ensure good ventilation of closed areas. Liquid remains treat with appropriate sorbent material (sand, diatomaceous earth), get to closed and labeled container and dispose. Contaminated areas clean with water. Work under proper ventilation.

6.4. Reference to other sections

Personal protective equipment – section 8

Waste disposal – section 13

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Before handling read label/instructions. Avoid contact with eyes, around the eyes, mucous membranes of mouth and nose and intimate parts. Don't eat, drink or smoke during product handling. Wash hands after use. Use strictly with product designation.

Special measures for protection against fire and explosion:

Avoid contact with open flames, heat sources, direct sunlight.

Industrial hygiene

- ensure good ventilation (overall and local exhausted ventilation)
- ensure place for eyes and skin rinsing
- wash hands with soap and water before eating, smoking and after work
- use general caution while working with chemical substances

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7.2. Conditions for safe storage, including any incompatibilities

Keep only in the original container, away from children. Avoid direct sunlight. Do not store or transport in temperatures above 40°C.

7.3. Specific end use(s)

See section 1.2.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational Exposure Limit Value:

There is no exposure standard allocated to hazardous components of this product.

DNELs (Derived No Effect Levels) for mixture components:

Route of exposure	Workers				General population (consumers)			
	Acute local Effects	Acute systemic effects	Chronic local effects	Chronic systemic effects	Acute local Effects	Acute systemic effects	Chronic local effects	Chronic systemic effects
Ingestion	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.
Inhalation	n. d.	n. d.	n. d.	13936 mg/m ³	n. d.	n. d.	n. d.	2476 mg/m ³
Dermal	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.

n. d. – no data

8.2. Exposure controls

8.2.1. Appropriate engineering controls: adequate ventilation

8.2.2. Individual protection measures, such as personal protective equipment

a) Respiratory protection – is not necessary under normal conditions with sufficient ventilation, required during exposure to high concentrations of vapours.

b) Hand protection – recommended protective gloves in case of prolonged or frequently repeated exposure to the product. Wear protective gloves made of: butyl rubber, neoprene, nitrile rubber, polyvinylchloride, thickness min. 0,4 – 0,7mm. The Breakthrough Time > 480 min. Material of gloves must be resistant to the product. As the product is a mixture of several substances, the resistance of material of gloves can not be calculated in advance and therefore has to be checked before use. From the manufacturer's advice should be obtained information about the time of the penetration of substances and such time must be respected. The Breakthrough Time indicated by the manufacturer must exceed the period during which the product is being used. It is recommended to change gloves and replace them immediately if you notice any signs of wear, damage (rupture, perforation) or changes in appearance (color, flexibility, shape).

c) Eye protection – recommended protective glasses

d) Skin protection – recommended protective clothing

Protective equipment standards:

EN 140:2001 Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking

EN 143:2004 Respiratory protective devices - Particle filters - Requirements, testing, marking

EN 149+A1:2010 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

EN 14387+A1:2010 Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking

EN 374-1:2005 Protective gloves against dangerous chemicals and micro-organisms -- Part 1: Terminology and performance requirements for chemical risks

EN 374-2:2005 Protective gloves against chemicals and micro-organisms - Part 2: Determination of resistance to penetration

EN 374-3:2005 Protective gloves against chemicals and micro-organisms – Part 2: Determination of resistance to permeation by chemicals

PN-EN 166:2005 Personal eye protection. Specifications



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PN-EN 14605+A1:2010 Protective clothing against liquid chemicals. Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

PN-EN ISO 20344:2012 Personal protective equipment -- Test methods for footwear

Environmental exposure controls.

Product isn't hazardous to the environment, special exposure controls are not required.

PNECs (Predicted No Effect Concentrations) for mixture components:

Compartment	
Fresh water	100 µg/L
Sediment – fresh water	750 µg/kg sediment dw
Marine water	10 µg/L
Sediment – marine water	No data
Intermittent releases (freshwater)	1 mg/L
Food chain	No data
Biological sewage treatment plant	73 mg/L
Soil (agriculture)	No data
Air	No data

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Aerosol
Odour:	Odourless
Odour threshold:	Not applicable
pH:	No data
Melting point/freezing point:	Not applicable
Initial boiling point and boiling range:	Not applicable
Flash point:	Not applicable
Evaporation rate:	Not applicable
Flammability:	Not applicable
Upper/lower flammability or explosive limits:	Not applicable
Vapour pressure:	Not applicable
Vapour density:	Not applicable
Density (20°C):	Not applicable
Solubility in water:	Not applicable
Partition coefficient: n-octanol/water:	Not applicable
Auto-ignition temperature:	Not applicable
Decomposition temperature:	Not applicable
Viscosity:	Not applicable
Explosive properties:	None, no explosive ingredients
Oxidising properties:	None, no oxidising ingredients

9.2. Other information

No data

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Product is not reactive in normal conditions of storage and handling

10.2. Chemical stability:

Product stable in normal conditions (see Section 7 – storage conditions)

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10.3. Possibility of hazardous reactions:

No data

10.4. Conditions to avoid:

Temperature above 40°C, direct sunlight

10.5. Incompatible materials:

No data

10.6. Hazardous decomposition products:

No hazardous decomposition products if stored and handled as prescribed/indicated.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects:

Classification was conducted by calculation method according to Regulation 1272/2008 based on mixture ingredients.

Acute toxicity:

Oral toxicity: product does not meet criteria for classification, $ATE_{mix} > 2000$ mg/kg

Dermal toxicity: product does not meet criteria for classification, $ATE_{mix} > 2000$ mg/kg

Inhalation toxicity: product does not meet criteria for classification, $ATE_{mix} > 5$ mg/l

Skin corrosion/irritation: product does not meet criteria for classification

Serious eye damage/irritation: product does not meet criteria for classification

Respiratory or skin sensitisation: product does not meet criteria for classification

Germ cell mutagenicity: product does not contain any compounds with germ cell mutagenicity hazard

Carcinogenicity: product does not contain any compounds with carcinogenic hazard

Reproductive toxicity: product does not contain any compounds with reprotoxic hazard

STOT-single exposure: no data available

STOT-repeated exposure: no data available

Aspiration hazard: no data available

Potential health effects:

Ingestion – not known

Inhalation – not known

Skin – not known

Eyes – not known

Available toxicological data for 1,1,1,2-Tetrafluoroethane:

Acute inhalation toxicity

LC₅₀ - rat - 4 h - 1.500.000 mg/m³

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity:

Classification was conducted by calculation method according to Regulation 1272/2008 based on mixture ingredients

Product isn't classified as harmful to the aquatic environment.

Available ecotoxicological data for 1,1,1,2-Tetrafluoroethane:

Acute toxicity:

Toxicity to fish: semi-static; LC₅₀/96 h - *Oncorhynchus mykiss* (rainbow trout) - 450 mg/L

Toxicity to invertebrates: semi-static EC₅₀/48 h - *Daphnia magna* (water flea) - 980 mg/L

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12.2. Persistence and degradability:

No data for the product

Available data for 1,1,1,2-Tetrafluoroethane:

Oxygen biodegradability: exposure 28 days; result: 3 % not readily biodegradable

12.3. Bioaccumulative potential:

No data

12.4. Mobility in soil:

No data

12.5. Results of PBT and vPvB assessment: product doesn't meet the criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation.

12.6. Other adverse effects:

Not known

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods:

Waste of product: Dispose of waste in accordance with all national regulations in plants permitted to waste collection, transport, waste recovery and disposal. Do not introduce waste of product into sewage.

Disposing of the packaging: Completely emptied product packaging can be treated as municipal waste.

SECTION 14: TRANSPORT INFORMATION

Product is supplied in 9 mL volume aerosol dispenser. Product is not subject to regulations regarding transport of dangerous goods as per relevant Special provisions (see below):

14.1. UN number: 1950

14.2. UN proper shipping name:

ADR, AEROSOLS, asphyxiant
IATA DGR, AEROSOLS, NON-FLAMMABLE
IMDG Code AEROSOLS

14.3. Transport hazard class(es):

ADR, 2
IATA DGR, 2.2
IMDG Code 2



14.4. Packing group:

ADR, IATA DGR, IMDG Code Not applicable

14.5. Environmental hazards:

ADR, IATA DGR, IMDG Code No

14.6. Special precautions for user:

Avoid temperatures above 40°C
 Classification code: 5A
 Labels: 2.2
 Hazard identification No: not applicable
 Packing instructions: P207, LP02
 Transport category (tunnel restriction code): 3 (E)

Special provision 190: Aerosols dispensers shall be provided with protection against inadvertent discharge. Aerosols with a capacity not exceeding 50 mL containing only non-toxic constituents are not subject

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to the requirements of ADR

Air transport (IATA DGR) Proper shipping name/description: Aerosols, non-flammable
Hazard Label: Non-flamm. gas
Passenger and Cargo Aircraft PI: 203
Cargo Aircraft Only PI: 203

Special provision A98: Aerosols, gas cartidges and receptacles, small containing gas with a capacity not exceeding 50 mL containing no constituents subject to these Regulations other than a Division 2.2 gas, are not subject to these Regulations when carried as cargo unless their release could cause extreme annoyance or discomfort to crew members so as to prevent the correct performance of duties.

The words "Not restricted" and the Special Provision number must be included in the description of the substance on the Air Waybill as required by 8.2.6, when Air Waybill is issued

See transport (IMDG): Emergency Schedule: F-D, S-U
Stowage and Handling: SW1, SW22
Segregation: SG69
Special provision 190: Aerosol dispensers shall be provided with protection against inadvertent discharge. Aerosols with a capacity not exceeding 50 mL containing only non-toxic constituents are not subject to the provisions of this Code.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council from 18.12.2006 concerning the Registration, Evaluation, Authorization and Restriction from Chemicals (REACH)
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- European agreement concerning international road transport of dangerous products (ADR)
- DIRECTIVE 2012/18/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC
- *Federal, State and Local regulations.*

15.2. Chemical safety assessment

Chemical safety assessment was not made for the product

SECTION 16. OTHER INFORMATION

Explanation of abbreviations and acronyms used in the MSDS:

H280 Contains gas under pressure; may explode if heated.

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CAS – Chemical Abstracts Service

EINECS – Number assigned to a substance in the European Inventory of Existing Commercial Chemical Substances

LD50 – lethal dose of 50% of tested population

LC50 – lethal concentration of 50% of tested population

PBT – persistence, bioaccumulation potential and toxicity

vPvB – very high durability and very bioaccumulative

UN number – identification number of the material (the number of UN, UN number)

ADR – European Agreement concerning the international carriage of dangerous goods by road

MSDS was prepared in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Classification of mixture was based on the content of hazardous components in accordance with the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Training: Personnel should be trained prior to handling of the product.

Recommendations and restrictions on use: Use according to the label-instruction.

Additional safety information available from the manufacturer.

Source of data: this MSDS was prepared based on MSDS of ingredients, data of product, our knowledge and experience according to actual legislation.

IUCLID International Uniform Chemical Information Database

C&L Inventory

Toxicological data for the product

Disclaimer: information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. End user is responsible for inappropriate use of information enclosed in MSDS or inappropriate use of product.

Edition 2.4, Section 14 – information update