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SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1. Product identifier

Tradename: **DERGALL**

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

1.2.1. Identified uses:

Physical mode of action formulation for control of red poultry mite (*Dermanyssus gallinae*).

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:

+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 regulation (EC) 1272/2008:

Acute toxicity (inhalation), category 4 with H phrase:

H332 Harmful if inhaled

Eye irritation, category 2 with H phrase:

H319 Causes serious eye irritation

Hazardous to the aquatic environment, chronic category 2 with H phrase:

H411 Toxic to aquatic life with long lasting effects

Health hazards: harmful if inhaled, irritating in contact with eyes.

Environmental hazards: toxic to aquatic life, may cause long lasting adverse effect to aquatic environment

Physical hazards: none

Fire hazards: product does not contains any flammable substances

Additional information:

Working solution (emulsion of 0,6%) does not cause eye irritation

2.2. Label elements


According to regulation (EC) 1272/2008:

Pictograms:



GHS07 GHS09

Signal words: **WARNING**

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Hazard Statement:

H319 Causes serious eye irritation
 H332 Harmful if inhaled
 H411 Toxic to aquatic life with long lasting effects

Precautionary statement:

General:

P101 If medical advice is needed, have product container or label at hand
 P102 Keep out of reach of children.

Prevention:

P261 Avoid breathing mist/vapours/spray.
 P273 Avoid release to the environment
 P280 Wear protective gloves/protective clothing/eye protection/face protection

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P337 + P313 If eye irritation persists: Get medical advice/attention.

Storage:

-

Disposal:

P501 Dispose of contents/container to point authorized to receive hazardous waste

2.3. Other hazards:

Product does not meet the criteria for PBT or vPvB according to Annex XIII of REACH regulation

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures.

Product is a mixture

Product contains polymeric silica compound, silanes, siloxanes

Composition: hazardous compound: silica copolymer: polyalkyleneoxide modified heptamethyltrisiloxane (CAS 67674-67-3)


Classification of product hazardous compound is given according to Table 3.1 of Annex VI of regulation EC 1272/2008, data generated and used for REACH registration and/or based on information provided by suppliers.

Content of hazardous compounds (non-hazardous compounds not affecting the classification are not mentioned):

Chemical name	CAS No/ EC No	REACH Registration No	Index No	Content	Hazard class and hazard statement
Polyalkyleneoxide modified heptamethyltrisiloxane	CAS: 67674-67-3 EC: none	Not applicable*	None	< 65 % w/w	Acute Tox. 4 (inhal.), H332 Eye Irrit. 2, H319 Aquatic Chronic 2, H411

* - polymer

Meaning of hazards classes and categories and full H phrases are given in Section 16.

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures.

General recommendations:

Stop the contact/exposure. In case of product causing indisposition immediately call for professional medical service. Show the label or safety data sheet to the physician/paramedic. Inform the physician/paramedic of first aid measures given to the victim. Do not give anything by mouth to the victim. In no case do not induce vomiting. If victim is vomiting place him in safe position to prevent the risk of choking. Remove clothing contaminated with the product

Skin contamination: wash contaminated skin with water and soap. In case of skin irritation get medical help. Contaminated clothing has to be washed before reuse.

Eye contamination: rinse widely open eyes with clean water or dedicated fluid for 15 minutes, get medical help if needed.

Inhalation exposure: remove the victim from exposure area, when breathing difficulties provide oxygen, get medical help if needed.

Ingestion: rinse mouth with plenty of water, get medical help immediately.

Protection of person providing first aid: Do not take any action, which may bring risk to anyone, unless one is properly medically trained. Person providing aid should avoid prolonged contact with the product without appropriate personal protection measures (see Section 8). Immediately remove contaminated clothing.

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

Acute symptoms – eye irritation (lachrymation, reddening)

Delayed symptoms – not applicable

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

Information for the physician: no known antidote, treat symptomatically.

In case of contact with emergency phone number of manufacturer or medical services, get product labelled packaging or this safety data sheet.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media.

Suitable extinguishing media: for small fires use foam, snow or powder extinguisher. For large fires use foam or water mist.


Unsuitable extinguishing media: strong stream of water.

5.2. Special hazards arising from the substance or mixture.

During the fire of the product following compounds might be emitted – carbon oxides, silica oxides, formaldehyde, other hazardous gases. Avoid breathing of combustion products, they might be hazardous to health.

5.3. Advice for firefighters:

Unconditionally use personal breathing apparatus and wear appropriate protective clothing during firefighting and cleaning after the fire inside closed and poorly ventilated rooms.

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General advice: evacuate all unauthorized personnel not taking action during firefighting. Call fire brigade in needed.

Additional remarks: containers and packages endangered by fire or high temperature should be cooled down by water from a safe distance (explosion risk), or relocated from area of fire if possible and safe. Fire residues and contaminated extinguishing media has to be disposed according to current regulation. Do not dispose extinguishing media to sewers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

Avoid contact with released product. Protect eyes and skin. Use recommended personal protection measures.

6.2. Environmental precautions:

Do not allow the product to get to the sewers, ground and surface waters. Do not rinse product to the sewers. In case of water contamination - inform appropriate authorities immediately.

6.3. Methods and material for containment and cleaning up:

In case of unsealed container or spillage secure source of contamination and move product to empty container. Spillages should be treated by appropriate sorbent (sand, diatomaceous earth), gathered to closed container and safely disposed. Area of spillage should be rinsed by water. Cleaning up should be conducted under appropriate ventilation.

6.4. Reference to other sections:

Personal protection measures – Section 8

Waste management – Section 13

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling:

Read label before use of the product. Avoid direct contact with mouth, skin and eyes. Do not eat or drink during product handling. Wash hands and face after usage. Product should be used only according to its purpose.

Special precautions against fire and explosion:

Avoid the risk of electrostatic discharge, do not expose to sparks, open fire, other sources of possible combustion.

Industrial hygiene:

- sufficient ventilation of work area is recommended (general and local exhaust ventilation)
- provide place for eye and wash cleaning in case of contamination
- wash hands by water and soap before eating, smoking and after work end.
- follow common safety precautions of chemicals handling


7.2. Conditions for safe storage, including any incompatibilities:

Keep product containers tightly closed and away from children.

Avoid contact with food and fodder.

7.3. Specific end use(s):

See Section 1.2.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters:

Threshold exposure limits: product does not contain any compounds for which threshold levels should be monitored in working area. TLV – not applicable

8.2. Exposure controls:

Technical control measures:

Local exhaust ventilation removing product vapours is obligatory, as well as general area ventilation.

Individual protection measures:

a) respiratory protection – in normal working conditions under sufficient ventilation respiratory protection is not required, unless high product vapours concentration occurs. Use masks or half-masks with typ A absorber. In case of low oxygen level (below 17 % v/v) or when product vapour concentration is above 1 % v/v use autonomic or stationary isolating equipment.

b) hand protection – use of protective gloves is recommended. Gloves material has to be impermeable and resistant to the product. Neoprene or nitrile rubber of 0.4 mm thickness might be sufficient. If prolonged contact with the product is foreseen – gloves of class 5 protection (according to EN 374) should be used. For shorter contact periods class 3 would be sufficient (breakthrough time above 60 min).

Resistance of glove material to the product should be checked before use. Glove manufacturer might provide data of breakthrough time of the product with glove material – in such case glove manufacturer information must be followed. Regular glove replacement is recommended. Obligatory replacement is due when any signs of damage (tear, puncture) occurs or any change in glove appearance (colour, shape, flexibility).

c) Eye protection – protective glasses with side shielding are required. If any risk of splashing, use full face protection gear.

d) skin protection – appropriate protective clothing is recommended during handling of the product.


Environmental exposure controls:

Do not allow the product to get to the soil, surface and ground water.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Appearance:	liquid, red coloured
Odour:	faint, delicate
Odour threshold:	no data
pH:	no data
Melting point/freezing point:	no data
Initial boiling point and boiling range:	no data
Flash point:	> 100°C
Evaporation rate:	no data
Flammability:	not applicable
Upper/lower flammability or explosive limits:	no data
Vapour pressure:	no data
Vapour density:	no data
Relative density:	1.01 – 1.02
Solubility in water:	insoluble, at 0.2% emulsifies
Partition coefficient: n-octanol/water:	no data
Auto-ignition temperature:	no data
Decomposition temperature:	no data
Viscosity:	no data
Explosive properties:	none
Oxidising properties:	none

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9.2. Other information: no data

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Not applicable.

10.2. Chemical stability:

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

10.3. Possibility of hazardous reactions:

Not applicable.

10.4. Conditions to avoid:

High temperatures, direct sunlight

10.5. Incompatible materials:

No data

10.6 Hazardous decomposition products:

Not applicable in normal conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects:

Classification of the product was conducted by calculation method according to regulation 1272/2008 based on the content of hazardous ingredients:

Acute toxicity (estimated):

Acute Oral Toxicity: based on data available classification criteria are not met

Acute Dermal Toxicity: based on data available classification criteria are not met

Acute Inhalation Toxicity: based on data available classification criteria are not met

Skin corrosion/irritation: based on data available classification criteria are not met

Serious eye damage/irritation: product classified as irritating to eyes (category 2)

Respiratory or skin sensitization: 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

STOT-repeated exposure: no data

Aspiration hazard: no data

Potential health effects:

Ingestion – may cause digestive system irritation

Inhalation – product is harmful, may cause irritation to respiratory system.

Skin – may cause irritation, sensitisation symptoms, may be harmful when absorbed by skin

Eyes – may cause conjunctiva irritation and reddening, may cause lachrymation

Toxicological data for product hazardous compound (polymeric silica compounds):

Acute toxicity, oral (rat): LD₅₀ > 2000 mg/kg


Acute toxicity, dermal (rat): LD₅₀ > 4000 mg/kg

Acute toxicity, inhalation (rat): LC₅₀ = 2 mg/dm³ (aerosol)

Acute toxicity, inhalation (rat): LC₅₀ = 11.78 mg/dm³ (aerosol – 5% water emulsion)

Skin irritation (rabbit): moderately irritating

Eye irritation (rabbit): highly irritating

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Working solution (0.3 and 0.6 %) of the product does not met any criteria for classification as hazardous to humans or animals.

SECTION 12: Ecological information

12.1. Toxicity:

Classification of the product was conducted by calculation method according to regulation 1272/2008 based on the content of hazardous ingredients.

Classified as toxic to aquatic life with long lasting effects, category 2.

12.2. Persistence and degradability:

Siloxanes are removed from water by sedimentation and adsorption onto sludge. In soil siloxanes undergo degradation.

12.3. Bioaccumulative potential: no data

12.4. Mobility in soil: no data

12.5. Results of PBT and vPvB assessment:

Product does not met the criteria for PBT or vPvB according to Annex XIII of REACH regulation

12.6. Other adverse effects:

Product is classified as toxic to aquatic life with long lasting effects. Make every effort to ensure the product from getting into the soil, drinking water sources, water reservoirs etc.

Ecotoxicological data for product hazardous compound (polymeric silica compounds):

Acute toxicity to fish (*Oncorhynchus mykiss*) LC₅₀ (96 h): 4.5 mg/dm³

Acute toxicity to aqueous invertebrates (*Daphnia magna*) EC₅₀ (48 h): 24 mg/dm³

NOEC (96h) (*Oncorhynchus mykiss*): 3,2 mg/dm³

NOEC (48h) (*Daphnia magna*): 5,6 mg/dm³

SECTION 13: Disposal considerations

13.1. Waste treatment methods:

Wastes of the product: Unused remains keep in original containers. Consult the manufacturer of the product on the possibility of waste processing. If not possible, get the wastes to the establishment authorized for transport, recovery and disposal of wastes. Do not enter product remains to the sewers.


Disposal of empty packaging: incineration of packages on the ground surface is prohibited. Do not use empty packaged as recyclable material, but treat them like any municipal waste.

Waste code: 15 01 10 - packaging containing residues of or contaminated by dangerous substances.

SECTION 14: TRANSPORT INFORMATION

- 14.1. UN number: 3082
 14.2. UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCES, LIQUID, N.O.S (Polyalkyleneoxide modified heptamethyltrisiloxane)
 14.3. Transport hazard class(es): 9
 14.4. Packing group: III
 14.5. Environmental hazards: Yes
 14.6. Special precautions for user:



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Road transport (ADR) Classification code: M6
 Labels: 9
 Hazard identification No: 90
 Packing instructions: P001, IBC03, LP01, R001
 Transport category (tunnel restriction code): 3 (E)

Special provision 375: These substances when carried in single or combination packagings containing a net quantity per single or inner packaging of 5 l or less for liquids or having a net mass per single or inner packaging 5 kg or less for solids, are not subject to any other provisions of ADR provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8

Air transport (IATA DGR) Class or Div.: 9
 Hazard Label: Miscellaneous
 Passenger and Cargo Aircraft PI: 964
 Cargo Aircraft Only PI: 964

Special provision A197: These substances when carried in single or combination packagings containing a net quantity per single or inner packaging of 5 l or less for liquids or having a net mass per single or inner packaging 5 kg or less for solids, are not subject to any other provisions of these Regulations provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8

See transport (IMDG): EmS codes: F-A, S-F
 Marine pollutant: yes

Provision 2.10.2.7 of IMDG CODE:


“Marine pollutants packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass per single or inner packaging of 5 kg or less for solids are not subject to any other provisions of this Code relevant to marine pollutants provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
 In the case of marine pollutants also meeting criteria for inclusion in another hazard class, all provision of this Code relevant to any additional continue to apply”

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

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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

Directive 2012/18/UE:

Named dangerous substances - ANNEX I none of the product ingredients is listed

Seveso category E2 Hazardous to the Aquatic Environment

Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of lower-tier requirements - 200 t

Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of upper-tier requirements - 500 t

15.2. Chemical safety assessment:

Chemical safety assessment was not conducted for the product.

SECTION 16: OTHER INFORMATION

Explanation of risk phrases and hazard category referring hazardous substance contained in product:

Acute Tox. 4 (inh) acute toxicity by inhalation, category 4

Eye Irrit. 2, irritating to eyes, category 2

Aquatic Chronic 2, substance dangerous to aquatic life, chronic, category 2

H319 Causes serious eye irritation

H332 Harmful if inhaled

H411 Toxic to aquatic life with long lasting effects

Explanation of abbreviations and acronyms used in the SDS:

CAS – Chemical Abstracts Service

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

PBT – persistence, bioaccumulation potential and toxicity

vPvB – very high durability and very bioaccumulative

TLV – threshold limit value in the workplace

STEL – short term exposure limits maximum of a substance harmful to health in the workplace

LD₅₀ – Lethal Dose, 50%

LC₅₀ – Lethal Concentration, 50%

EC₅₀ – Effect Concentration 50%

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

IMDG – International Maritime Dangerous Goods Code


SDS 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 made based on the content of hazardous components according to the Regulation (EC) No 1272/2008 as well as on study data obtained for the product.

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

Recommendation and restriction of use: Use according to label. Additional safety information available at producer.

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

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ECHA European Chemicals Agency

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 4.0 changes:

Section 11 and 12 – information update

Section 14 and 15 – additional data provided

Section 1-16 – editorial changes