

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	Alpha Flux 100 mg/ml concentrate for solution for fish treatment
Registration number	-
Synonyms	Alpha Flux 100 mg/ml * Alpha Flux 100 mg/ml concentrate for solution * ALPHA FLUX®, Hexaflumuron 100 mg/mL
Issue date	06-May-2020
Version number	01

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

Identified uses	Veterinary product for use in aquaculture
Uses advised against	Not for human use

1.3. Details of the supplier of the safety data sheet

Company name:	PHARMAQ AS (part of Zoetis)
Office address:	Industrivegen 50
Postal address:	Skogmo Industriområde NO-7863 Overhalla, Norway
Phone number:	+47 74 28 08 00
Fax number:	+47 74 28 08 01
Email:	customer.service@pharmaq.no
Website:	http://www.pharmaq.no

Emergency telephone number:	Norway (Giftinformasjonen): +47 22 59 13 00 United Kingdom: 999 or 112 Italy: 112 Spain (Servicio De Información Toxicológica): +34 91 562 04 20 International CHEMTREC (24 hours): +1-703-527-3887
Additional emergency telephone number:	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards

Skin corrosion/irritation	Category 2	H315 - Causes skin irritation.
Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.
Reproductive toxicity (the unborn child)	Category 1B	H360D - May damage the unborn child.
Specific target organ toxicity - single exposure	Category 3 respiratory tract irritation	H335 - May cause respiratory irritation.

Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard	Category 1	H410 - Very toxic to aquatic life with long lasting effects.
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Hazard summary Causes serious eye irritation. Causes skin irritation. May cause irritation to the respiratory system. May cause reproductive effects. Dangerous for the environment if discharged into watercourses. Occupational exposure to the substance or mixture may cause adverse health effects.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains:	Hexaflumuron, N-methyl-2-pyrrolidone
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Hazard pictograms



Signal word

Danger

Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing mist/vapor.
P264	Wash thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response

P308 + P313	IF exposed or concerned: Get medical advice/attention.
P302 + P352	IF ON SKIN: Wash with plenty of water.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTRE/doctor if you feel unwell.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.

Storage

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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Supplemental label information Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.3. Other hazards The mixture contains a substance that is assessed to be a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
N-methyl-2-pyrrolidone	30-60	872-50-4 212-828-1	-	606-021-00-7	#
Classification:	Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335, Repr. 1B;H360D				
Hexaflumuron	5-15	86479-06-3 617-865-0	-	616-221-00-6	
Classification:	Aquatic Acute 1;H400(M=1000), Aquatic Chronic 1;H410(M=10000)				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).

M: M-factor

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulative substance.

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.
4.1. Description of first aid measures	
Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. Call a poison centre or doctor/physician if you feel unwell. For breathing difficulties, oxygen may be necessary.
Skin contact	Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Get medical advice/attention if you feel unwell. Wash contaminated clothing before reuse.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
4.2. Most important symptoms and effects, both acute and delayed	Irritant effects. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis. May cause respiratory irritation. Coughing. Shortness of breath. Prolonged exposure may cause chronic effects.
4.3. Indication of any immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards	Combustible. Material will burn in a fire.
5.1. Extinguishing media	
Suitable extinguishing media	Alcohol resistant foam. Powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
5.2. Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed. Material will burn in a fire. Vapours may ignite.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures	
For non-emergency personnel	Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Keep unnecessary personnel away. Ensure adequate ventilation. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Ventilate the contaminated area. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
6.2. Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Ensure adequate ventilation. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep combustibles (wood, paper, oil etc) away from spilled material. Wear appropriate protective equipment and clothing during clean-up. Prevent product from entering drains. Prevent entry into waterways, sewer, basements or confined areas. Large Spills: Stop the flow of material, if this is without risk. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Clean surface thoroughly to remove residual contamination. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Use only with adequate ventilation. Wear personal protective equipment. Combustible. Keep away from heat and sources of ignition. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Do not empty into drains. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed original container in a dry, cool and well-ventilated place. Do not handle or store near an open flame, heat or other sources of ignition. Do not store in direct sunlight. Do not freeze. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s)

Veterinary antiparasitic.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Zoetis

Components

Hexaflumuron (CAS 86479-06-3)

Type

TWA

Value

290 µg/m³

Austria. MAK List, OEL Ordinance (GwV), BGBl. II, no. 184/2001

Components

N-methyl-2-pyrrolidone (CAS 872-50-4)

Type

MAK

Value

40 mg/m³

Form

Vapour.

10 ppm

Vapour.

STEL

80 mg/m³

Vapour.

20 ppm

Vapour.

Belgium. Exposure Limit Values.

Components

N-methyl-2-pyrrolidone (CAS 872-50-4)

Type

STEL

Value

80 mg/m³

20 ppm

TWA

40 mg/m³

10 ppm

Bulgaria. OELs. Regulation No 13 on protection of workers against risks of exposure to chemical agents at work

Components

N-methyl-2-pyrrolidone (CAS 872-50-4)

Type

STEL

Value

80 mg/m³

20 ppm

TWA

40 mg/m³

10 ppm

Croatia. Dangerous Substance Exposure Limit Values in the Workplace (ELVs), Annexes 1 and 2, Narodne Novine, 13/09

Components

N-methyl-2-pyrrolidone (CAS 872-50-4)

Type

MAC

Value

40 mg/m³

10 ppm

STEL

80 mg/m³

20 ppm

Czech Republic. OELs. Government Decree 361

Components

N-methyl-2-pyrrolidone (CAS 872-50-4)

Type

Ceiling

Value

80 mg/m³

TWA

40 mg/m³

Denmark. Exposure Limit Values

Components

N-methyl-2-pyrrolidone (CAS 872-50-4)

Type

TLV

Value

20 mg/m³

Denmark. Exposure Limit Values

Components	Type	Value
		5 ppm

Estonia. OELs. Occupational Exposure Limits of Hazardous Substances. (Annex of Regulation No. 293 of 18 September 2001)

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m ³
		20 ppm
	TWA	40 mg/m ³ 10 ppm

Finland. Workplace Exposure Limits

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m ³
		20 ppm
	TWA	40 mg/m ³ 10 ppm

France. Threshold Limit Values (VLEP) for Occupational Exposure to Chemicals in France, INRS ED 984

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	VLE	80 mg/m ³
	Regulatory status: Regulatory indicative (VRI)	20 ppm
	Regulatory status: Regulatory indicative (VRI)	40 mg/m ³
	VME	40 mg/m ³
Regulatory status: Regulatory indicative (VRI)		10 ppm
Regulatory status: Regulatory indicative (VRI)		

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
N-methyl-2-pyrrolidone (CAS 872-50-4)	TWA	82 mg/m ³	Vapour and aerosol.
		20 ppm	Vapour and aerosol.

Germany. TRGS 900, Limit Values in the Ambient Air at the Workplace

Components	Type	Value	Form
N-methyl-2-pyrrolidone (CAS 872-50-4)	AGW	82 mg/m ³	Vapour.
		20 ppm	Vapour.

Greece. OELs (Decree No. 90/1999, as amended)

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m ³
		20 ppm
	TWA	40 mg/m ³ 10 ppm

Hungary. OELs. Joint Decree on Chemical Safety of Workplaces

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m ³
	TWA	40 mg/m ³

Iceland. OELs. Regulation 154/1999 on occupational exposure limits

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Ireland. Occupational Exposure Limits

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Italy. Occupational Exposure Limits

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Latvia. OELs. Occupational exposure limit values of chemical substances in work environment

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Lithuania. OELs. Limit Values for Chemical Substances, General Requirements

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Luxembourg. Binding Occupational exposure limit values (Annex I), Memorial A

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Malta. OELs. Occupational Exposure Limit Values (L.N. 227. of Occupational Health and Safety Authority Act (CAP. 424), Schedules I and V)

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Netherlands. OELs (binding)

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3

Netherlands. OELs (binding)

Components	Type	Value
	TWA	40 mg/m3

Norway. Administrative Norms for Contaminants in the Workplace

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TLV	20 mg/m3 5 ppm

Ordinance of the Minister of Labour and Social Policy on 6 June 2014 on the maximum permissible concentrations and intensities of harmful health factors in the work environment, Journal of Laws 2014, item 817

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
	TWA	40 mg/m3

Portugal. OELs. Decree-Law n. 290/2001 (Journal of the Republic - 1 Series A, n.266)

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Romania. OELs. Protection of workers from exposure to chemical agents at the workplace

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Slovakia. OELs. Regulation No. 300/2007 concerning protection of health in work with chemical agents

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Slovenia. OELs. Regulations concerning protection of workers against risks due to exposure to chemicals while working (Official Gazette of the Republic of Slovenia)

Components	Type	Value	Form
N-methyl-2-pyrrolidone (CAS 872-50-4)	TWA	40 mg/m3	Vapour.
		10 ppm	Vapour.

Spain. Occupational Exposure Limits

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m3
		20 ppm
	TWA	40 mg/m3 10 ppm

Sweden. OELs. Work Environment Authority (AV), Occupational Exposure Limit Values (AFS 2015:7)

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	Ceiling	80 mg/m3

Sweden. OELs. Work Environment Authority (AV), Occupational Exposure Limit Values (AFS 2015:7)

Components	Type	Value
		20 ppm
	TWA	40 mg/m ³
		10 ppm

Switzerland. SUVA Grenzwerte am Arbeitsplatz

Components	Type	Value	Form
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	160 mg/m ³	Vapour and aerosol.
		40 ppm	Vapour and aerosol.
	TWA	80 mg/m ³	Vapour and aerosol.
		20 ppm	Vapour and aerosol.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m ³
		20 ppm
	TWA	40 mg/m ³
		10 ppm

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
N-methyl-2-pyrrolidone (CAS 872-50-4)	STEL	80 mg/m ³
		20 ppm
	TWA	40 mg/m ³
		10 ppm

Biological limit values

Croatia. BLV. Dangerous Substance Exposure Limit Values at Workplace, Annexes 4 (as amended)

Components	Value	Determinant	Specimen	Sampling Time
N-methyl-2-pyrrolidone (CAS 872-50-4)	70 mg/g	5-Hydroxy-N-methyl-2-pyrrolidone	Creatinine in urine	*
	20 mg/g	2-Hydroxy-N-methylsuccinimide	Creatinine in urine	*

* - For sampling details, please see the source document.

Germany. TRGS 903, BAT List (Biological Limit Values)

Components	Value	Determinant	Specimen	Sampling Time
N-methyl-2-pyrrolidone (CAS 872-50-4)	150 mg/l	5-Hydroxy-N-methyl-2-pyrrolidone	Urine	*

* - For sampling details, please see the source document.

Spain. Biological Limit Values (VLBs), Occupational Exposure Limits for Chemical Agents, Table 4

Components	Value	Determinant	Specimen	Sampling Time
N-methyl-2-pyrrolidone (CAS 872-50-4)	70 mg/g	5-Hidroxi-N-metil-2-pirrolidona	Creatinine in urine	*
	20 mg/g	2-Hidroxi-N-metilsuccinimida	Creatinine in urine	*

* - For sampling details, please see the source document.

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no effect levels (DNELs) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines NMP (CASRN 872-50-4): DNEL: Derived No Effect Level.
ECHA: European Chemical Agency.
Inhalation. 14,4 mg/m³. Dermal 4,8 mg/kg/day.

EU Exposure Limit Values: Skin designation

N-methyl-2-pyrrolidone (CAS 872-50-4) Can be absorbed through the skin.

Slovenia. OELs. Regulations concerning protection of workers against risks due to exposure to chemicals while working (Official Gazette of the Republic of Slovenia)

N-methyl-2-pyrrolidone (CAS 872-50-4) Can be absorbed through the skin.

8.2. Exposure controls

Appropriate engineering controls Avoid exposure - obtain special instructions before use. Ensure adequate ventilation, especially in confined areas. Provide adequate general and local exhaust ventilation. Ensure compliance with applicable exposure limits. Eye wash facilities and emergency shower must be available when handling this product.

Individual protection measures, such as personal protective equipment

General information Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection Wear tight-fitting goggles or face shield. (Ref: EN 166).

Skin protection

- Hand protection REACH: Risk Management Measures for Workers - Dermal
Wear appropriate chemical resistant gloves. Impervious gloves. Neoprene. Nitrile.
(Ref: BS-EN 374, BS-EN 420).

- Other REACH: Risk Management Measures for Workers - Dermal
Wear appropriate chemical resistant clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection REACH: Risk Management Measures for Workers - Inhalation
Do not breathe dust/fume/gas/mist/vapours/spray. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
(Ref: EN 143). (Ref: EN 14387).

Thermal hazards Not applicable.

Hygiene measures Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental exposure controls Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Liquid.
Form Liquid.
Colour Clear. Opaque. yellowish.

Odour Not available.

Odour threshold Not available.

pH 3 - 4,5 (diluted 1:1 in water)

Melting point/freezing point 147 - 150 °C (296,6 - 302 °F)

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density	Not available.
Solubility(ies)	
Solubility (water)	insoluble in cold water
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	30 mPa·s @ 20C
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

9.2. Other information

Density	1,08 g/cm ³
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SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials. High temperatures. Sunlight. Moisture. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Protect from freezing.
10.5. Incompatible materials	Strong oxidising agents. Strong bases. Strong acids. Reducing Agents. Combustible material.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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Information on likely routes of exposure

Inhalation	May cause irritation to the respiratory system. Prolonged inhalation may be harmful.
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Skin contact	Causes skin irritation. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis. May be absorbed through the skin and cause systemic effects.
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Hexaflumuron	OECD 404 Result: Irritant Species: Rabbit Severity: Slight
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Eye contact	Causes serious eye irritation.
Hexaflumuron	OECD 405 Result: Irritant Species: Rabbit Severity: Slight

N-methyl-2-pyrrolidone	Species: Rabbit Severity: Moderate
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Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
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Symptoms	Irritant effects. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause respiratory irritation. Coughing. Prolonged exposure may cause chronic effects.
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11.1. Information on toxicological effects

Acute toxicity	Not acutely toxic.
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Components	Species	Test Results
Hexaflumuron (CAS 86479-06-3)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 7 mg/l/4h

Components	Species	Test Results
Oral		
LD50	Rat	> 5000 mg/kg
NOAEL	Hen	5000 mg/kg No evidence of delayed neurotoxicity
Chronic		
Oral		
NOAEL	Dog	0,5 mg/kg/day, 52 weeks Blood
	Mouse	25 mg/kg/day, 80 weeks Not carcinogenic
	Rat	75 mg/kg/day, 104 weeks Not carcinogenic
		75 mg/kg/day, 52 weeks Blood, Liver
Subacute		
Oral		
LOAEL	Dog	25 mg/kg/day, 28 days Blood
NOAEL	Mouse	25 mg/kg/day, 28 days Blood, Liver
Subchronic		
Oral		
NOAEL	Mouse	5 mg/kg/day, 90 days Blood, Liver
	Rat	25 mg/kg/day, 90 days Blood
N-methyl-2-pyrrolidone (CAS 872-50-4)		
Acute		
Dermal		
LD50	Rabbit	8000 mg/kg
Oral		
LD50	Mouse	7725 mg/kg
	Rat	3914 mg/kg
Chronic		
Inhalation		
NOEL	Rat	0,4 mg/l, 2 years Not carcinogenic
Subacute		
Oral		
NOAEL	Mouse	2500 ppm, 28 days Kidney
	Rat	6000 ppm, 28 days None identified
Skin corrosion/irritation	Causes skin irritation.	
Corrosivity		
Hexaflumuron		OECD 404 Result: Irritant Species: Rabbit Severity: Slight
Serious eye damage/eye irritation	Causes serious eye irritation.	
Eye contact		
Hexaflumuron		OECD 405 Result: Irritant Species: Rabbit Severity: Slight
N-methyl-2-pyrrolidone		Species: Rabbit Severity: Moderate
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.	
Skin sensitisation	Based on available data, the classification criteria are not met. This product is not expected to cause skin sensitisation.	
Skin sensitisation		
Hexaflumuron		OECD 406 Result: negative Species: Guinea pig

Germ cell mutagenicity	Based on available data, the classification criteria are not met.	
Mutagenicity		
N-methyl-2-pyrrolidone		Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella
Hexaflumuron		Bacterial mutagenicity Result: negative
		In vitro chromosomal aberration Result: negative
		In vitro mammalian cell mutagenicity (CHO/HGPRT) Result: negative
		In vivo mouse micronucleus Result: negative Species: Mouse
Carcinogenicity	Based on available data, the classification criteria are not met.	
Hungary. 26/2000 EüM Ordinance on protection against and preventing risk relating to exposure to carcinogens at work (as amended)		
Not listed.		
Reproductive toxicity	May damage the unborn child.	
Developmental effects		
N-methyl-2-pyrrolidone		0,36 mg/l Embryo / Fetal Development, Maternal Toxicity Not Teratogenic Result: NOEL Species: Rat Organ: Inhalation
Hexaflumuron		1000 mg/kg/day OECD 414, No effects on dams or fetuses Result: NOAEL Species: Rabbit Organ: Oral
		1000 mg/kg/day OECD 414, No effects on dams or fetuses Result: NOAEL Species: Rat Organ: Oral
N-methyl-2-pyrrolidone		237 mg/kg Embryo / Fetal Development, Maternal Toxicity Fetotoxicity Not Teratogenic Result: NOAEL Species: Rat Organ: Dermal
Reproductivity		
N-methyl-2-pyrrolidone		237 mg/kg/day Reproductive & Fertility, Maternal toxicity Fetotoxicity Result: NOEL Species: Rat Organ: Dermal
Hexaflumuron		25 mg/kg/day 2-Gen Reproduction Toxicity (OECD 416), Reproductive effects (offspring mortality) Result: NOAEL Species: Rat Organ: Oral
		5 mg/kg/day 2-Gen Reproduction Toxicity (OECD 416), Parental toxicity (blood effects) Result: NOAEL Species: Rat Organ: Oral
Specific target organ toxicity - single exposure	May cause respiratory irritation.	
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met. This product may affect Hematopoietic System. Blood. Liver. Kidneys. through prolonged or repeated exposure.	

Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
Mixture versus substance information	No information available
Other information	CAUTION! Parasiticide.

SECTION 12: Ecological information

12.1. Toxicity Very toxic to aquatic life with long lasting effects. Avoid release to the environment.

Components	Species	Test Results
Hexaflumuron (CAS 86479-06-3)		
	EC50	Activated sludge > 100 mg/l, 3 hours
Aquatic		
Algae	ErC50	Pseudokirchneriella subcapitata (Green Alga) > 1,91 mg/l, 96 hours
<i>Acute</i>		
Crustacea	EC50	Daphnia magna 0,11 µg/l, 48 hours
Fish	LC50	Lepomis macrochirus (Bluegill Sunfish) > 0,141 mg/l, 96 hours Oncorhynchus mykiss (rainbow trout) > 0,489 mg/l, 96 hours
<i>Chronic</i>		
Crustacea	NOEC	Daphnia magna 0,0029 µg/l, 21 days

12.2. Persistence and degradability No data is available on the degradability of this product. The following information is available for the individual ingredients.

Photolysis

Half-Life (Photolysis-Aqueous)

Hexaflumuron 6,3 days US EPA guideline 161-2, T1/2 @ 25C / pH 5

Hydrolysis

Half-Life (Hydrolysis-Acidic)

Hexaflumuron US EPA guideline 161-1, @ 25C / pH 5
Result: Stable

Half-Life (Hydrolysis-Basic)

Hexaflumuron 22 days US EPA guideline 161-1, DT50 @ 25C / pH 9
Result: 60%

Half-Life (Hydrolysis-Neutral)

Hexaflumuron 270 days US EPA guideline 161-1, DT50 @ 25C / pH 7
Result: 6%

Biodegradability

Percent Degradation (Aerobic Biodegradation)

Hexaflumuron 4,1 - 6 % OECD 301B
Result: Not readily biodegradable
Test Duration: 29 days

Percent Degradation (Aerobic Biodegradation-Soil)

Hexaflumuron DT50, 280 days @ 12C/54F

12.3. Bioaccumulative potential No data available for this product. The following information is available for the individual ingredients.

Partition coefficient n-octanol/water (log Kow)

Hexaflumuron 5,68, @ 20C/68F

Bioconcentration factor (BCF)

Hexaflumuron 3783 - 7667 US EPA guideline 165-4
Species: Lepomis macrochirus (Bluegill Sunfish)

12.4. Mobility in soil No data available for this product. The following information is available for the individual ingredients.

Adsorption

Soil/Sediment Sorption - Log Koc

Hexaflumuron 3,86 US EPA EPI Suite

- 12.5. Results of PBT and vPvB assessment** The mixture contains a substance that is assessed to be a PBT or a vPvB.
- 12.6. Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Residual waste** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
- Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.
- EU waste code** The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
EWC: 02 01 08.
EWC: 18 02 05.
- Disposal methods/information** Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not discharge into drains, water courses or onto the ground. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
- Special precautions** Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

- 14.1. UN number** UN3082
- 14.2. UN proper shipping name** Environmentally hazardous substance, liquid, n.o.s.
(1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea)
- 14.3. Transport hazard class(es)**
- Class** 9
 - Subsidiary risk** -
 - Label(s)** 9
 - Hazard No. (ADR)** 90
 - Tunnel restriction code** -
- 14.4. Packing group** III
- 14.5. Environmental hazards** yes
- 14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

RID

- 14.1. UN number** UN3082
- 14.2. UN proper shipping name** Environmentally hazardous substance, liquid, n.o.s.
(1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea)
- 14.3. Transport hazard class(es)**
- Class** 9
 - Subsidiary risk** -
 - Label(s)** 9
- 14.4. Packing group** III
- 14.5. Environmental hazards** yes
- 14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

ADN

- 14.1. UN number** UN3082
- 14.2. UN proper shipping name** Environmentally hazardous substance, liquid, n.o.s.
(1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea)
- 14.3. Transport hazard class(es)**
- Class** 9
 - Subsidiary risk** -
 - Label(s)** 9
- 14.4. Packing group** III
- 14.5. Environmental hazards** yes
- 14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

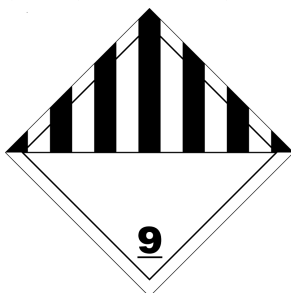
IATA

14.1. UN number	UN3082
14.2. UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	YES
ERG Code	9L
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

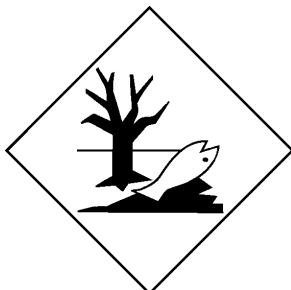
IMDG

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea), MARINE POLLUTANT
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

ADN; ADR; IATA; IMDG; RID



Marine pollutant



General information

IMDG Regulated Marine Pollutant. As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

N-methyl-2-pyrrolidone (CAS 872-50-4)

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

N-methyl-2-pyrrolidone (CAS 872-50-4)

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Hexaflumuron (CAS 86479-06-3)

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations

Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended.

Follow national regulation on the protection of workers from the risks of exposure to carcinogens and mutagens at work, in accordance with Directive 2004/37/EC.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

Not available.

Information on evaluation method leading to the classification of mixture

The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature. The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360D May damage the unborn child.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Transport Information: Product Shipping Name/Packing Group
GHS: Classification
DNELs: Printed DNELs

Training information

Follow training instructions when handling this material.

Disclaimer

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.