

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

1.1. Product identifier

Product form : Mixture
Product name : EA50 Papanicolaou solution
Product code : 367600

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

1.2.1. Relevant identified uses

Main use category : For professional use only
Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS
Site Montesquieu
33650 MARTILLAC - FRANCE
T 33 05 57 96 04 04 - F 33 05 57 96 04 05
commercial@ral-diagnostics.fr - www.ral-diagnostics.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2 H225
Acute toxicity (oral), Category 4 H302
Acute toxicity (dermal), Category 4 H312
Acute toxicity (inhalation:vapour) Category 4 H332
Specific target organ toxicity — single exposure, Category 1 H370
Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. Causes damage to organs. Harmful in contact with skin. Harmful if inhaled. Harmful if swallowed.

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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Contains

: Methanol

Hazard statements (CLP)

: H225 - Highly flammable liquid and vapour.
H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled.
H370 - Causes damage to organs.

Precautionary statements (CLP)

: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 - Wash hands thoroughly after handling.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.
P312 - Call a POISON CENTRE or doctor if you feel unwell.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl alcohol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	50 - 80	Flam. Liq. 2, H225
Methanol substance with national workplace exposure limit(s) (GB, IE, MT); substance with a Community workplace exposure limit	(CAS-No.) 67-56-1 (EC-No.) 200-659-6 (EC Index-No.) 603-001-00-X (REACH-no) 01-2119433307-44	25 - 50	Flam. Liq. 2, H225 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 STOT SE 1, H370

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Methanol	(CAS-No.) 67-56-1 (EC-No.) 200-659-6 (EC Index-No.) 603-001-00-X (REACH-no) 01-2119433307-44	(3 ≤ C < 10) STOT SE 2, H371 (10 ≤ C < 100) STOT SE 1, H370

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

: IF exposed or concerned: Get medical advice/attention. Call a poison center or a doctor if you feel unwell.

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First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	: Rinse skin with water/shower. Take off immediately all contaminated clothing.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Rinse mouth. Call a poison center or a doctor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact with skin, eyes and clothing.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear personal protective equipment. Do not breathe dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Use only outdoors or in a well-ventilated area.
Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Storage temperature : 15 – 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Ethyl alcohol (64-17-5)	
Ireland - Occupational Exposure Limits	
Local name	Ethanol [Ethyl alcohol]
OEL STEL [ppm]	1000 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m ³
WEL TWA (OEL TWA) [2]	1000 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

Methanol (67-56-1)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Methanol
IOEL TWA	260 mg/m ³
Notes	skin
Regulatory reference	COMMISSION DIRECTIVE 2006/15/EC
Ireland - Occupational Exposure Limits	
Local name	Methanol [Methyl alcohol]
OEL TWA [1]	260 mg/m ³
OEL TWA [2]	200 ppm
Notes (IE)	Sk (Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body), IOELV (Indicative Occupational Exposure Limit Values)
Regulatory reference	Chemical Agents Code of Practice 2020
Malta - Occupational Exposure Limits	
Local name	Methanol
OEL TWA	260 mg/m ³
OEL TWA [ppm]	200 ppm
Remark (MT)	Skin # Ġilda
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.57 of 2018)
United Kingdom - Occupational Exposure Limits	
Local name	Methanol
WEL TWA (OEL TWA) [1]	266 mg/m ³
WEL TWA (OEL TWA) [2]	200 ppm

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Methanol (67-56-1)	
WEL STEL (OEL STEL)	333 mg/m ³
WEL STEL (OEL STEL) [ppm]	250 ppm
Remark (WEL)	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
[In case of inadequate ventilation] wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Green.
Odour	: alcoholic.
Odour threshold	: No data available
pH	: 5.5 – 6
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: $\approx 80\text{ }^{\circ}\text{C}$
Flash point	: $15.23\text{ }^{\circ}\text{C}$
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at $20\text{ }^{\circ}\text{C}$: No data available
Relative density	: 0.823
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Harmful in contact with skin.

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Acute toxicity (inhalation) : Harmful if inhaled.

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ATE CLP (oral)	381.388 mg/kg bodyweight
ATE CLP (dermal)	1144.165 mg/kg bodyweight
ATE CLP (vapours)	11.442 mg/l/4h

Ethyl alcohol (64-17-5)	
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560
LD50 oral	8300 mg/kg bodyweight Animal: mouse
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat	> 20 mg/l

Methanol (67-56-1)	
LD50 oral rat	1187 – 2769 mg/kg bodyweight Animal: rat
LD50 dermal rabbit	300 mg/kg Source: ECHA
LC50 Inhalation - Rat (Vapours)	131.5 mg/l/4h

Skin corrosion/irritation : Not classified
pH: 5.5 – 6

Serious eye damage/irritation : Not classified
pH: 5.5 – 6

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Ethyl alcohol (64-17-5)	
IARC group	1 - Carcinogenic to humans

Reproductive toxicity : Not classified

Methanol (67-56-1)	
LOAEL (animal/male, F0/P)	1700 mouse
NOAEL (animal/male, F0/P)	< 1000 mg/kg bodyweight Animal: mouse, Animal sex: male

STOT-single exposure : Causes damage to organs.

Methanol (67-56-1)	
STOT-single exposure	Causes damage to organs.

STOT-repeated exposure : Not classified

Ethyl alcohol (64-17-5)	
NOAEL (subchronic, oral, animal/male, 90 days)	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)

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Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Ethyl alcohol (64-17-5)	
LC50 - Fish [1]	14.2 g/l Test organisms (species): Pimephales promelas
EC50 72h - Algae [1]	1900 – 1970 mg/l (marine water)
EC50 96h - Algae [1]	275 mg/l (freshwater)
ErC50 algae	275 mg/l Source: ECHA
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'
NOEC chronic fish	250 mg/l

Methanol (67-56-1)	
LC50 - Fish [1]	15400 mg/l Source: ECHA
EC50 - Crustacea [1]	> 10000 mg/l Daphnia magna
EC50 96h - Algae [1]	22000 mg/l Source: ECHA
NOEC (chronic)	208 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	15800 mg/l Oryzias latipes

12.2. Persistence and degradability

Ethyl alcohol (64-17-5)	
Persistence and degradability	Readily biodegradable.

Methanol (67-56-1)	
Persistence and degradability	Readily biodegradable.

12.3. Bioaccumulative potential

Ethyl alcohol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.32 Source: ICSC
Bioaccumulative potential	No bioaccumulation.

Methanol (67-56-1)	
Partition coefficient n-octanol/water (Log Pow)	-0.77 Source: HSDB, CHemIDplus
Bioaccumulative potential	No bioaccumulation.

12.4. Mobility in soil

Methanol (67-56-1)	
Mobility in soil	2.75 Source: HSDB

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12.5. Results of PBT and vPvB assessment

Component	
Methanol (67-56-1)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Other adverse effects : Not release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions. Dispose in a safe manner in accordance with local/national regulations.

Additional information : Flammable vapours may accumulate in the container.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN 1992	UN 1992	UN 1992	UN 1992	UN 1992
14.2. UN proper shipping name				
FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethyl alcohol ; Methanol)	FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethyl alcohol ; Methanol)	Flammable liquid, toxic, n.o.s. (Ethyl alcohol ; Methanol)	FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethyl alcohol ; Methanol)	FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethyl alcohol ; Methanol)
Transport document description				
UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethyl alcohol ; Methanol), 3 (6.1), II, (D/E)	UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethyl alcohol ; Methanol), 3 (6.1), II	UN 1992 Flammable liquid, toxic, n.o.s. (Ethyl alcohol ; Methanol), 3 (6.1), II	UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethyl alcohol ; Methanol), 3 (6.1), II	UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethyl alcohol ; Methanol), 3 (6.1), II
14.3. Transport hazard class(es)				
3 (6.1)	3 (6.1)	3 (6.1)	3 (6.1)	3 (6.1)
14.4. Packing group				
II	II	II	II	II
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available				

14.6. Special precautions for user

Overland transport

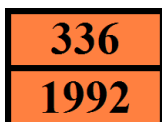
Classification code (ADR) : FT1
Special provisions (ADR) : 274
Limited quantities (ADR) : 1I

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Excepted quantities (ADR)	: E2
Packing instructions (ADR)	: P001, IBC02
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T7
Portable tank and bulk container special provisions (ADR)	: TP2
Tank code (ADR)	: L4BH
Tank special provisions (ADR)	: TU15
Vehicle for tank carriage	: FL
Transport category (ADR)	: 2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28
Special provisions for carriage - Operation (ADR)	: S2, S22
Hazard identification number (Kemler No.)	: 336
Orange plates	:



Tunnel restriction code (ADR)	: D/E
EAC code	: •3WE
APP code	: A(fl)

Transport by sea

Special provisions (IMDG)	: 274
Limited quantities (IMDG)	: 1 L
Excepted quantities (IMDG)	: E2
Packing instructions (IMDG)	: P001
IBC packing instructions (IMDG)	: IBC02
Tank instructions (IMDG)	: T7
Tank special provisions (IMDG)	: TP2, TP13
EmS-No. (Fire)	: F-E
EmS-No. (Spillage)	: S-D
Stowage category (IMDG)	: B
Stowage and handling (IMDG)	: SW2
Properties and observations (IMDG)	: Flammable toxic liquid which is not specified by name in this class or, on account of its characteristics, in some other class. Toxic if swallowed, by skin contact or by inhalation.
MFAG-No	: 131

Air transport

PCA Excepted quantities (IATA)	: E2
PCA Limited quantities (IATA)	: Y341
PCA limited quantity max net quantity (IATA)	: 1L
PCA packing instructions (IATA)	: 352
PCA max net quantity (IATA)	: 1L
CAO packing instructions (IATA)	: 364
CAO max net quantity (IATA)	: 60L
Special provisions (IATA)	: A3
ERG code (IATA)	: 3HP

Inland waterway transport

Classification code (ADN)	: FT1
Special provisions (ADN)	: 274, 802
Limited quantities (ADN)	: 1 L

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Excepted quantities (ADN) : E2
Equipment required (ADN) : PP, EP, EX, TOX, A
Ventilation (ADN) : VE01, VE02
Number of blue cones/lights (ADN) : 2

Rail transport

Classification code (RID) : FT1
Special provisions (RID) : 274
Limited quantities (RID) : 1L
Excepted quantities (RID) : E2
Packing instructions (RID) : P001, IBC02
Mixed packing provisions (RID) : MP19
Portable tank and bulk container instructions (RID) : T7
Portable tank and bulk container special provisions (RID) : TP2
Tank codes for RID tanks (RID) : L4BH
Special provisions for RID tanks (RID) : TU15
Transport category (RID) : 2
Special provisions for carriage - Loading, unloading and handling (RID) : CW13, CW28
Colis express (express parcels) (RID) : CE7
Hazard identification number (RID) : 336

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:			
Section	Changed item	Change	Comments
	Revision date	Modified	
	Supersedes	Modified	
14.1	UN-No. (IMDG)	Modified	
14.1	UN-No. (ADN)	Modified	
14.1	UN-No. (IATA)	Modified	
14.1	UN-No. (ADR)	Modified	

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Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3

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Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Flam. Liq. 2	Flammable liquids, Category 2
STOT SE 1	Specific target organ toxicity — single exposure, Category 1
STOT SE 2	Specific target organ toxicity — Single exposure, Category 2
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H331	Toxic if inhaled.
H332	Harmful if inhaled.
H370	Causes damage to organs.
H371	May cause damage to organs.

The classification complies : ATP 12
with

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.