

Alcohol ketonated 70%

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 04/04/2012 Revision date: 08/03/2017

445983

Version: 2.0

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

1.1. Product identifier

Product form : Mixtures
Product name : Alcohol ketonated 70%
Product code : 445983
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

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

Full text of hazard classes and H-statements : see section 16

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Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)



GHS02

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H225 - Highly flammable liquid and vapour

Precautionary statements (CLP)

: P210 - Keep away from heat, hot surfaces, open flames, sparks. - No smoking
P233 - Keep container tightly closed

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 Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol 96% V/V	(CAS No) 64-17-5 (EC No) 200-578-6 (EC Index No) 603-002-00-5 (REACH-no) 01-2119457610-43	66.0877 5	F; R11	Flam. Liq. 2, H225
Purified water	(CAS No) 7732-18-5 (EC No) 231-791-2	33.5	Not classified	Not classified
2-Butanone	(CAS No) 78-93-3 (EC No) 201-159-0 (EC Index No) 606-002-00-3	0.33	F; R11 Xi; R36 R66 R67	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336

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Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Bergamot oil		0.05	Not classified	Skin Irrit. 2, H315 Skin Sens. 1A, H317 Asp. Tox. 1, H304 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Denatonium benzoate	(CAS No) 3734-33-6 (EC No) 223-095-2	0.00225	Not classified	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures**4.1. Description of first aid measures**

First-aid measures after inhalation : Assure fresh air breathing.
First-aid measures after skin contact : Rinse with plenty of water.
First-aid measures after eye contact : Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
First-aid measures after ingestion : If you feel unwell, seek medical advice.

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

No additional information available

SECTION 5: Fire-fighting measures**5.1. Extinguishing media**

Suitable extinguishing media : Carbon dioxide. Dry powder. Foam.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : This product is flammable.

5.3. Advice for firefighters

No additional information available

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****6.1.1. For non-emergency personnel**

Emergency procedures : Ensure adequate air ventilation.

6.1.2. For emergency responders

No additional information available

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6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak if safe to do so.

Methods for cleaning up : Dam up the liquid spill. Take up liquid spill into inert absorbent material.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Keep away from sources of ignition. Protect from sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Not required

Respiratory protection:

None necessary

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state : Liquid

Appearance : Clear.

Colour : Colourless.

Odour : Characteristic.

Odour threshold : No data available

pH : No data available

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Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: 22 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Miscible with : Alcohol. 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

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Ethanol 96% V/V (64-17-5)	
LD50 oral rat	6200 mg/kg
LD50 oral	6300 mg/kg bodyweight rabbit

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2-Butanone (78-93-3)	
LD50 oral rat	2737 mg/kg
LD50 dermal rabbit	6480 mg/kg
Denatonium benzoate (3734-33-6)	
LD50 oral rat	584 mg/kg
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information**12.1. Toxicity**

Ethanol 96% V/V (64-17-5)	
LC50 fish 1	11200 mg/l 24h (Oncorhynchus mykiss, US EPA E03-05)
LC50 fish 2	13000 mg/l 96h (Oncorhynchus mykiss, OECD 203)
LC50 other aquatic organisms 1	275 mg/l 72h (Chlorella vulgaris, OECD 201)
EC50 Daphnia 1	12340 mg/l 48 h.
EC10	12 mg/l/72h (Chlorella vulgaris, OECD 201)
bacteria (Pseudomonas putida)	toxic limit concentration: 6500 mg/l
Activated sludge	Damage from 15 g / l
Behaviour in sewage treatment plants	EC50 > 1000 mg/l

2-Butanone (78-93-3)	
LC50 fish 1	3130 - 3230 mg/l Pimephales promelas 96 h
EC50 Daphnia 1	520 mg/l 48 h

12.2. Persistence and degradability

Ethanol 96% V/V (64-17-5)	
Persistence and degradability	readily degradable in water.
Biochemical oxygen demand (BOD)	0.93 - 1.67 g O ₂ /g substance
Chemical oxygen demand (COD)	1.99 g O ₂ /g substance
ThOD	2.1 g O ₂ /g substance
BOD (% of ThOD)	90 % ThOD

12.3. Bioaccumulative potential

Ethanol 96% V/V (64-17-5)	
Log Pow	- 0.31
Bioaccumulative potential	Slightly or not bioaccumulative.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

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12.6. Other adverse effects

No additional information available


SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
1987	1987
14.2. UN proper shipping name	
ALCOHOLS, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
3	3
	Not applicable
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

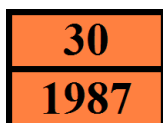
14.6. Special precautions for user**- Overland transport**

Classification code (ADR) : F1

Excepted quantities (ADR) : E1

Hazard identification number (Kemler No.) : 30

Orange plates :



Tunnel restriction code (ADR) : D/E

EAC code : •3Y

- Air transport

No data available

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

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Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

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:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources

: 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. Supplier.

Full text of R-, H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Asp. Tox. 1	Aspiration hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1A	Sensitisation — Skin, category 1A
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H225	Highly flammable liquid and vapour
H302	Harmful if swallowed
H304	May be fatal if swallowed and enters airways
H315	Causes skin irritation
H317	May cause an allergic skin reaction

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H319	Causes serious eye irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

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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