

Milton® Sterilising Tablets

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: Milton® Sterilising tablets UFI : 13V0-V1GX-X00U-7H28

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

Disinfectant

1.3. Details of the supplier of the safety data sheet

Registered company name: Milton International Address: 9 rue Marcel Sembat, 44100 Nantes - France Phone: +33 (0)5 49 68 15 15 Fax.: +33 (0)5 49 66 16 41 E-mail: <u>fds@labo-rivadis.fr</u> <u>https://www.milton-tm.com/en</u>

Registered company name: Milton Pharmaceutical Company UK Ltd Address: The Garden Suite, 23 Westfield Park, Redland, BS6 6LT, Bristol - England Phone: +44 0800 097 5606 E-mail: <u>fds@labo-rivadis.fr</u> <u>https://www.milton-tm.com/en</u>

1.4. Emergency telephone number

Country	Phone number	Website
Austria	112	-
Belgium	+ 32 070 245 245	http://www.centreantipoisons.be/
Bulgaria	+359 2 9154 409	http://www.pirogov.bg
Croatia	(+385 1) 23-48-342	-
Cyprus	112	-
Czech Republic	+420 224 919 293, +420 224 915 402	www.tis-cz.cz
Denmark	+45 82 12 12 12	-
Estonia	16662 / (+372) 626 93 90	-
Finland	112	-
France	+33 (0)1 45 42 59 59	INRS / ORFILA http://www.centres-antipoison.net.
Germany	112	-
Greece	112	-
Hungary	+36 1 476 6464 / +36 80 201 199	-
Iceland	112	-
Ireland	01 809 2166	-
Italy	112	-
Latvia	+371 67042473	-
Liechtenstein	112	-
Lithuania	+370 5 236 20 52 / +370 687 53378	http://www.tox.lt/
Luxembourgs	112	-
Malta	112	-
Netherlands	(+31) 030-2748888	-
Norway	(+42) 2259 1300	-
Poland	112	-
Portugal	0808 250 143	-
Romania	112	-
Slovakia	(+421) 2 54 774 166	-
Slovenia	112	-
Spain	+ 34 91 562 04 20	-
Sweden	112	-
Switzerland	145	-
United Kingdom	111	-

SECTION 2 – HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Eye irritation	Eye Irrit. 2 - H319
Hazardous to the aquatic environment - Chronic hazard	Aquatic Chronic 2, H411

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazards pictograms:



SGH07 SGH09

Signal word: WARNING

Hazard statements:

H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements:

P101	If medical advice is needed, have product container or label at hand.	
P102	Keep out of reach of children.	
P264	Wash hands thoroughly after handling.	
P271	Use only outdoors or in a well-ventilated area.	
P273	Avoid release to the environment.	
P280	Wear eye protection.	
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.	
P391	Collect spillage.	
P402+P404	Store in a dry place. Store in a closed container.	
P405	Store locked up.	
P501	Dispose of contents/ container in accordance with local regulations.	
Additional laballing		

Additional labelling:

EUH031	Contact with acids liberates toxic gas.
EUH206	Warning! Do not use together with other products. May release dangerous gases (chlorine).
Contains	

Troclosène sodium

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) >= 0.1% published by the European CHemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006. The mixture does not contain substances> = 0.1% with endocrine disrupting properties in accordance with the criteria of the Delegated Regulation (EU) 2017/2100 of the Commission or Regulation (EU) 2018/605 of the Commission.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable (mixture).

3.2. Mixtures

Composition:

INDEX	CAS No.	EC No.	Hazardous ingredient(s)	Pictograms	Classification	% w/w
607-144-00-9	124-04-9	204-673-3	Adipic acid	GHS 07	H319	25-40
613-030-01-7	2893-78-9	220-767-7	Troclosene sodium	GHS 03 GHS 07	EUH031 H272	15-25

			M factor (Acute)= 1 M factor (Chronic) = 1	GHS 09	H302 H319 H335 H400 H410	
011-005-00-2	497-19-8	207-838-8	Sodium carbonate	GHS 07	H319	5-10

See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

SECTION 4 – FIRST AID MEASURES

4.1. Description of first aid measures

General information	In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.
In the event of exposure by upon breathing difficulties or irritation of the respiratory tract: Bring the person into fresh with him/her.	
In the event of splashes or contact with eyes	Upon irritation of the eye: Remove contact lenses. Flush eyes immediately with plenty of water or isotonic water (20-30°C) for at least 5 minutes and continue until irritation stops. Make sure to flush under upper and lower eyelids. If irritation continues, contact a doctor. Continue flushing during transport.
In the event of splashes or contact with skin	Upon irritation: rinse with water. In the event of continued irritation, seek medical assistance.
In the event of ingestion	Provide plenty of water for the person to drink and stay with him/her. In case of malaise, seek medical advice immediately and bring the safety data sheet or label from the product. Do not induce vomiting, unless recommended by the doctor. Have the victim lean forward with head down to avoid inhalation of- or choking on vomited material.

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

	This product contains substances, which may cause irritation upon exposure to skin, eyes or lungs. Exposure may result in an increased absorption potential of other hazardous substances at the area of exposure.
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4.3. Indication of any immediate medical attention and special treatment needed

If eye irritation persists	Get medical advice/attention.
Information to medics	Bring this safety data sheet or the label from this product.

SECTION 5 – FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Alcohol-resistant foam, carbon dioxide, powder, water mist. Unsuitable extinguishing media: Waterjets should not be used, since they can spread the fire.

5.2. Special hazards arising from the substance or mixture

Fire will result in dense smoke. Exposure to combustion products may harm your health. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-extinguishing water to enter the sewage system and nearby surface waters.

If the product is exposed to high temperatures, e.g. in the event of fire, dangerous decomposition compounds are produced. These are: - Carbon oxides (CO / CO2)

- Some metal oxides

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact. Upon direct exposure contact The National Poisons Information Service (dial 111, 24 h service) in order to obtain further advice.

Hazchem Code: 2Z

SECTION 6 – ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective clothing as described in Section 8 of this safety data sheet. Wear suitable protective equipment, including gloves, goggles/face shield, respirator, boots, clothing or apron, as appropriate. Ensure suitable respiratory protection is worn during removal of spillages in confined areas. Avoid inhalation of dust and contact with skin and eyes. Wash thoroughly after dealing with a spillage.

6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc. In the event of leakage to the surroundings, contact local environmental authorities.

6.3. Methods and material for containment and cleaning up

Minor spills are collected with a cloth. Collection and disposal of the material shall be done with minimum creation of dust. Sweep and collect. Shall be contained in suitable and tightly closed disposal containers.

Wherever possible cleaning should be performed with normal cleaning agents. Avoid use of solvents.

6.4. Reference to other sections

See section 13 "Disposal considerations" on handling of waste. See section 8 "Exposure controls/personal protection" for protective measures.

SECTION 7 – HANDLING AND STORAGE

7.1. Precautions for safe handling

Smoking, drinking and consumption of food is not allowed in the work area. See section 8 "Exposure controls/personal protection" for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage material	Keep only in original packaging.	
Storage temperature	e Ambient temperature and humidity, in original packaging securely closed	
Incompatible materials	Will not polymerise. The following materials may react with the product: Acids. Alkalis. Organic nitro compounds. Amines. Oxidising agents. Reducing agents. Moisture. Peroxides. Contact with acids liberates toxic gas. Under normal conditions of storage and use, no hazardous reactions will occur.	

7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No substances are listed in the national list of substances with an occupational exposure limit.

ADIPIC ACID (CAS: 124-04-9)

DNEL	Long term – Systemic effects - General population – Dermal : 7.5 mg/kg bw/day Long term – Systemic effects - Workers – Dermal : 21 mg/kg bw/day Long term – Systemic effects - General population – Inhalation : 13 mg/m ³ Long term – Systemic effects - Workers – Inhalation : 74.1 mg/m ³ Long term – Systemic effects - General population – Oral : 7.5 mg/kg bw/day
PNEC	 Freshwater - Continuous : 126 μg/L Freshwater sediment - Continuous : 474 μg/kg Intermittent release (freshwater)- Continuous : 460 μg/L Marine water - Continuous : 12.6 μg/L Marine water sediment - Continuous : 47.4 μg/kg Soil - Continuous : 20.8 μg/kg

SODIUM CARBONATE (CAS: 497-19-8)

	Long term – Systemic effects - General population – Inhalation : 5 mg/m ³
	Long term – Systemic effects - Workers – Inhalation : 10 mg/m ³

TROCLOSENE SODIUM (CAS: 2893-78-9)

DNEL	Long term – Systemic effects - General population – Dermal : 1.15 mg/kg bw/day Long term – Systemic effects - Workers – Dermal : 2.3 mg/kg bw/day Long term – Systemic effects - General population – Inhalation : 1.99 mg/m ³ Long term – Systemic effects - Workers – Inhalation : 8.11 mg/m ³ Long term – Systemic effects - General population – Oral : 1.15 mg/kg bw/day
PNEC	 Freshwater - Continuous : 170 ng/L Freshwater sediment - Continuous : 7.56 mg/kg Intermittent release (freshwater)- Continuous : 1.7 μg/L Marine water - Continuous : 1.52 mg/L Sewage treatment plant - Continuous : 590 μg/L Soil - Continuous : 756 μg/kg

8.2. Exposure controls

Control is unnecessary if the product is used as intended.

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General recommendations	Smoking, drinking and consumption of food is not allowed in the work area.	
Exposure scenarios	There are no exposure scenarios implemented for this product.	
Exposure limits	Occupational exposure limits have not been defined for the substances in this product.	
Appropriate technical measures	Apply standard precautions during use of the product. Avoid inhalation of gas or dust.	
Hygiene measures	In between use of the product and at the end of the working day all exposed areas of the body must be washed thoroughly. Always wash hands, forearms and face.	
Measures to avoid environmental exposure	Keep damming materials near the workplace. If possible, collect spillage during work. Keep container tightly sealed when not in use.	
8.3. Individual protection measur	es, such as personal protective equipment	
Generally	Use only UKCA marked protective equipment.	
Respiratory Equipment	No specific requirements	
Skin protection	Standard fabric garments (e.g. cotton overcoat or apron). However, in a professional setting, an in-	
	use risk assessment should determine what is suitable.	
Hand protection		
	Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible.	
Eye protection		
	Chemical splash goggles or face shield, if an in-use risk assessment specifies it is necessary	

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information:

Physical state	Tablet
Odor	Characteristic. Chlorine.
Color	White.

Important health, safety and environmental information:

рН	pH (diluted solution): 4-6 @ 1%
Density	1.4 g/cm³
Solubility in water	Completely soluble

9.2. Other information

Not determined.

SECTION 10 – STABILITY AND REACTIVITY

10.1. Reactivity

Contact with acids liberates toxic gas.

Warning! Do not use in combination with other products. May release dangerous gases (chlorine).

10.2. Chemical stability

The product is stable under the conditions, noted in section 7 "Handling and storage".

10.3. Possibility of hazardous reactions

Contact with acids liberates toxic gas. The following materials may react with the product: Alkalis. Organic nitro compounds. Amines. Oxidising agents. Reducing agents. Moisture. Peroxides. Under normal conditions of storage and use, no hazardous reactions will occur.

10.4. Conditions to avoid

Avoid the following conditions: Avoid heat, flames and other sources of ignition. Avoid exposure to high temperatures or direct sunlight.

10.5. Incompatible materials

Flammable/combustible materials. Moisture. Avoid contact with acids and alkalis. Avoid contact with strong oxidising agents. Avoid contact with strong reducing agents. Hydrocarbons. Inorganic nitrates. Inorganic nitrites. Organic compounds.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1. Heating may generate the following products: Carbon monoxide (CO). Oxides of nitrogen. Hydrogen chloride (HCI). Isocyanates. Chlorine.

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1. Substances

No data available

11.1.2. Mixture

Serious damage to eyes/eye irritation	Causes serious eye irritation.

11.2 Information on other hazards

Long term effects	Irritation effects: This product contains substances, which may cause irritation upon exposure to skin, eyes or lungs. Exposure may result in an increased absorption potential of other hazardous substances at the area of exposure.
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SECTION 12 – ECOLOGICAL INFORMATION

12.1. Toxicity

TROCLOSENE SODIUM (CAS: 2893-78-9)

Acute toxicity - fish Acute toxicity - aquatic invertebrates $LC_{50},$ 96 hours: 0.38 mg/l, Oncorhynchus mykiss $EC_{50},$ 48 hours: < 1 mg NaDCC mg/l, Daphnia magna

12.2. Persistence and degradability No data available.

12.3. Bioaccumulative potential No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

12.6. Endocrine disrupting properties

Not known.

12.7. Other adverse effects

This product contains substances that are toxic to the environment. May result in adverse effects to aquatic organisms. This product contains substances, which may cause adverse long-term effects to the aquatic environment.

SECTION 13 – DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods	Product is covered by the regulations on hazardous waste. HP 4 - Irritant (skin irritation and eye damage) HP 12 – Release of an acute toxic gas HP 14 – Ecotoxic Dispose of contents/container to an approved waste disposal plant. Regulation (EU) No 1357/2014 of 18 December 2014 on waste as retained and amended in UK law.	
EWC code	Disposal methods : Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority. General Information : Waste is classified as hazardous waste. Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.	
Specific labelling	Not applicable.	

Contaminated packing

ing Packaging containing residues of the product must be disposed of similarly to the product.

SECTION 14 – TRANSPORT INFORMATION

Additional information

These substances when carried in single or combination packaging's 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 ADR/IMDG/IATA provided the packaging's meet the general provisions of 4.1.1.1, 4.1.1.2, 4.1.1.4 - 4.1.1.8 (ADR, IMDG) / 5.0.2.4.1, 5.0.2.6.1.1, 5.0.2.8 (IATA).

ADR / See Table A, Section 3.2.1 for any information on special provisions, requirements, or warnings in connection with transport. See section 5.4.3, for instructions in writing regarding mitigation of damages in relation to incidents or accidents during transport.

IMDG / See section 3.2.1, for any information on special provisions, requirements, or warnings in connection with transport.

IATA / See Table 4.2 for any information on special provisions, requirements, or warnings in connection with transport.

This product is within scope of the regulations of transport of dangerous goods.

Hazchem Code: 2Z

14.1 UN number

UN No. (ADR)	3077
UN No. (IMDG)	3077
UN No. (IATA)	3077

14.2. UN proper shipping name

Proper shipping name (ADR)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Troclosene sodium)
Proper shipping name (IMDG)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Troclosene sodium)
Proper shipping name (IATA)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Troclosene sodium)

14.3. Transport hazard class(es)

Class	9
Classification code	M7
Label	9

Transport labels



14.4. Packing group	
ADR packing group	Ш
IMDG packing group	Ш
IATA packing group	Ш

14.5. Environmental hazards

- Environmentally hazardous substance/marine pollutant:



14.6. Special precautions for user

EmS	F-A, S-F
Tunnel restriction code	(-)

Limited quantities 5kg

14.7. Transport in bulk according according to IMO instruments

No data available.

SECTION 15 – REGULATORY INFORMATION

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

Restrictions for application	Restricted to professional users.
Demands for specific education	No specific requirements.
SEVESO - Categories / dangerous substances	E2 - ENVIRONMENTAL HAZARDS, Qualifying quantity (lower-tier): 200 tonnes / (uppertier): 500 tonnes
Biocidal Products Regulations	Product type: PT2 - Disinfectants and algaecides not intended for direct application to humans or animals Product type: PT4 - Food and feed area
Sources	Control of Major Accident Hazards (COMAH) Regulations 2015. In accordance with Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products as retained and amended in UK law. Regulation (EU) No 1357/2014 of 18 December 2014 on waste as retained and amended in UK law. Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) as retained and amended in UK law. Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as retained and amended in UK law.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16 – OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Title for H and EUH indications mentioned in section 3:

EUH031	Contact with acids liberates toxic gas.
H272	May intensify fire; oxidiser.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations

ADN	European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway
ADR	European agreement concerning the international carriage of dangerous goods by Road.
ATE	Acute Toxicity Estimate
BCF	Bioconcentration Factor

CAS	Chemical Abstracts Service
CE	Conformité Européenne
CLP	Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EINECS	European Inventory of Existing Commercial chemical Substances
ES	Exposure Scenario
EUH stateme nt	CLP-specific Hazard statement
EWC	European Waste Catalogue
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IARC	International Agency for Research on Cancer (IARC)
ΙΑΤΑ	International Air Transport Association.
IBC	Intermediate Bulk Container
IMDG	International Maritime Dangerous Goods.
LogPow	logarithm of the octanol/water partition coefficient
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, bioaccumulable and toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International carriage of Dangerous goods by rail.
RRN	REACH Registration Number
SCL	A specific concentration limit
SVHC	Substances of very high concern.
STOT- RE	Specific Target Organ Toxicity - Repeated Exposure
STOT- SE	Specific Target Organ Toxicity - Single Exposure
TWA	Time Weighted Averages
UN	United Nations
UVBC	Unknown or variable composition, complex reaction products or of biological materials
cov	Volatile Organic Compound
vPvB	Very persistent, very bioaccumulable.