

גליון בטיחות (לפי תקנות הבטיחות בעבודה [גליון בטיחות], התשנ"ח - 1998)



## SAFETY DATA SHEET

SECTION 1		פרק 1 זיהוי החומר המסוכן וזהות היצרן
Name of Product	<b>Klor-De Disinfecting Effervescent Tablets</b>	שם התכשיר / חומר
USE	Disinfectant for medical institutions and general purposes including medical equipment and surfaces. חומר חיטוי למוסדות רפואיים ושימוש כללי הכולל חיטוי וניקוי ציוד רפואי ומשטחים.	השימוש
MANUFACTURED by:	Concept for Pharmacy Ltd./ConRaD קונצפט לרוקחות בע"מ/קונרד	יצרן
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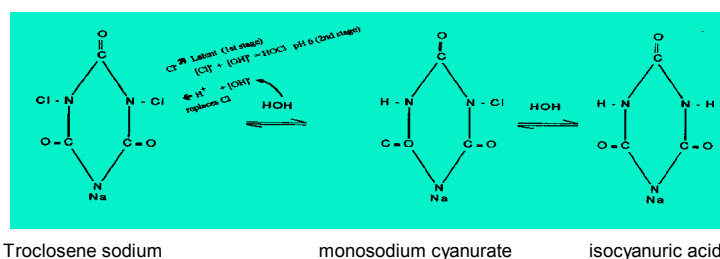
SECTION 2		פרק 2 זיהוי מרכיבי החומר המסוכן
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Product	<b>Klor-De Disinfecting Effervescent Tablets</b>	תכשיר
COMPOSITION:	Each tablet contains 800mg <b>Sodium Troclosene</b> in an effervescent base.	שם החומר הפעיל

ACTIVE INGREDIENT:	החומר הפעיל:	
GENERIC NAME	Troclosene Sodium	שם גנרי
CHEMICAL NAME:	1,3 - dichloro 1,3,5, triazine - 2,4,6 (1H,3H,5H) - trione.	שם הכימי
CHEMICAL FAMILY:	Organic chlorine donor.	משפחה כימית
FORMULA:	$\text{NaCl}_2(\text{NCO})_3$	פורמולה כימית
CAS No	2893-78-9	
Raw Material (Powder )	<b>In the finished product NOT considered Hazardous</b> <b>התכשיר לא נחשב כמסוכן</b>	
UN Number	# 2465	
EINECS	220-767-7	
SCIENTIFIC DATA regarding the active ingredient.	Troclosene sodium is sodium dichloro-s-triazinetriene / Sodium dichloroisocyanurate) is the sodium salt of 1,3-dichloro-1,3,5, triazine -2,4,6(1H,3H,5H)-trione. It is a white crystalline or granular powder, of molecular weight 219.9, containing about 60% latent available chlorine' having the formula $\text{C}_3\text{Cl}_2\text{N}_3\text{NaO}_3$ , sodium troclosene has the action and uses of chlorine but its activity is only slightly affected by pH over the range 5 - 8. On solution in water it is relatively stable with the formation of mono-sodium cyanurate and isocyanuric acid, both non-toxic and non-hazardous compounds.	

Structural formula & How TROCLOSENE works

מבנה כימי ואופן הפעולה של החומר :



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OTHER INGREDIENTS:		מרכיבים נוספים:	
INGREDIENT מרכיב	C.A.S.	PERMIT/GRADE	HAZARD סיכון
Adipic Acid	124-04-9	E 355 Compen. of Food Additives Spec. Addend. 7-1999	NON HAZARDOUS
Sodium Bicarbonate	144-55-8	E 500 Eur P	NON HAZARDOUS
Prussian Blue - ConRaDye Ferric Hexacyanoferrate	14038-43-8	This dye is a permitted colour for Pharmaceutical preparations under US code of Federal regulations Title 21 pt 73 Section 73.2299. It is also allowed for this purpose under Israel Ministry of Health regs (1995). CI # 77510/77520	NON HAZARDOUS The LD <sub>50</sub> of Ferric Hexacyanoferrate is > 10 g/Kg Per Os.
Colloidal silicon dioxide <b>AEROSIL®</b>	112945-52-5	According to the European Dangerous Substance Directive (67/548/EEC) and its amendments and adaptations. Can be used as additives in food, food contact material and products, and pharmaceutical applications.	NON HAZARDOUS
Sodium Lauril sulphate	151-21-3	Eur P	NON HAZARDOUS
Sodium sulphate		Eur P	NON HAZARDOUS
Chemical contaminants.	<p><b>מזהמים כימיים:</b> מאחר שכל המרכיבים מאיכות פארמקופאליה או FCC או CP, אין חשש של מזהם כימי בתרכובת.</p> <p>As all the ingredients (effervescent base-colour dye-detergent - tablet fillers) are approved as food or pharmaceutical additives, there are no extraneous chemical contaminants.</p>		
<b>SECTION 3 Inherent Dangers</b>		<b>פרק 3 סיכוני החומר המסוכן</b>	
<p>The use of Troclosen sodium is listed by the World Health Organisation in their report "<i>Water Supply Sanitation &amp; Health in Rural Areas</i>" published in 1991, Under the name of Aquatabs (known in Israel as Taharmayim) is approved for use world wide for <b>drinking water purification</b> United Nations Common Coding System) UNCCS #856461 and has been in use for many years by western armies including the Israel Defense Force, and aid organisations such as the Red Cross, UNICEF, and OXFAM.</p> <p>It is approved on 5th Feb 2002 by the NSF (National Science Foundation of the USA) for the use in public drinking water (ANSI Standard 60) and also for the same purpose in the United Kingdom in 2001.</p> <p>Non Poisonous, may come in contact with food. Approved for direct contact antiseptics of food by the Ministry of Health in Israel.</p> <p>The tablets contain less than 50% of this ingredient and therefore skin contact will cause no irritation or other side effects. The solution produced when the tablets are dissolved in water is intended for application to the skin, and was approved by the Ministry of Health for the <b>treatment of open wounds in humans</b>. Listed in Martindale 2002 (Klor De) for the disinfection of surgical apparatus.</p> <p>Chronic and subchronic studies show no significant toxicity.</p>			
<b>SECTION 4 First Aid</b>		<b>פרק 4 הוראות עזרה ראשונה</b>	
<p><b>Klor-De 800</b> tablets are not intended for oral administration. Should a tablet be ingested, no short or long term effects will result, other than a possible mildly upset stomach which will be <b>alleviated upon drinking small quantities of milk</b>. Isocyanurate derivatives are relatively non-irritant to open wounds, non-toxic even in extremely high doses. If solution or powder gets into the eyes, irrigate the eye with water.</p> <p><b>במקרה של אכילת כדור בשוגג - יש לשחות כוס חלב.</b></p> <p>Inhalation of the fumes produced on contact of the tablets with water. Remove to fresh air and instruct to breath deeply.</p>			
<b>SECTION 5 Fire hazard</b>		<b>פרק 5 נוהל כיבוי אש</b>	
<p>Product is non-combustible but will give off toxic fumes when heated. Packaging will burn if involved in a fire. Breathing apparatus must be worn when fighting fires. If safe to do so, remove undamaged containers from the fire area in order to minimise hazards from release of toxic fumes. Extinguish small fires with dry powder extinguishers. It will often be safer to let the fire burn itself out. where it is decided to fight the fire with water, LARGE volumes MUST be used.</p>			
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<b>SECTION 6 Precautions</b>	<b>פרק 6 אמצעי זהירות</b>
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**Klor-De** is presented as soluble effervescent tablets. They are innocuous if stored and used correctly. Do not allow to come in contact with acids, reducing materials, particularly any reactive liquid organic chemicals which have double bonds. If large quantities of tablets should come in contact with water, carbon dioxide is released together with some small amounts of chlorine. Inhalation of these vapours should be avoided.

<b>SECTION 7 Storage</b>	<b>פרק 7 טיפול ואחסנה</b>
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**Klor-De** should be stored in the original containers which should be kept closed at all times. To be stored in a dry, well aired place away from acids and chemicals which are reducing materials, particularly any reactive liquid organic chemicals which have double bonds. Do not be store near naked flames. Preferably the storage place should cool and not in sunlight.

<b>SECTION 8 Personal Protection</b>	<b>פרק 8 אמצעים לצמצום חשיפה ומיגון אישי</b>
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When using normal quantities of **Klor-De** tablets in accordance to the instructions, no special precautions or protective clothing is required.

If very large quantities of **Klor-De** tablets should come in contact with water, carbon dioxide is released together with some small amounts of chlorine. Inhalation of these vapours should be avoided. In such an emergency situation, personell dealing with "clean up" should wear gas masks. Although not strictly necessary protective clothing including rubber gauntlets and protective goggles may be worn.

<b>SECTION 9 Physical and chemical properties</b>	<b>פרק 9 תכונות פיסיקליות וכימיות</b>
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The finished product takes the form of flat round tablets Ø 18 mm and 7- 8 mm thick, and a weight of approximately 3 gms each. They have a light blue speckled appearance. In the dry state they are extremely stable. They are soluble in water to produce a very dark blue solution with the typical smell of the organic chlorine donor (oxidising agent) Troclosene sodium.

**ACTION of USE:** The active constituent of **Klor-De Disinfecting Effervescent Tablets** is an organic chlorine donor, Troclosene sodium. Similar tablets are registered under several brand names for use in the food industry to disinfect surfaces and machinery which comes in contact with food , for direct food disinfection, for general surface and equipment disinfection in medical institutions, as a general disinfectant for use in in hospitals and clinics, as a veterinary medicine in the prevention of mastitis, and as a human medicine for use on open wounds. Troclosene is also used for drinking water disinfection.

<b>SECTION 10 Stability and Reactivity</b>	<b>פרק 10 יציבות וריאקטיביות</b>
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Decomposes above 240°C with release of chlorine and other toxic fumes. Soluble in water slowly forming monosodium cyanurate, isocyanuric acid and a weak hypochlorous acid solution.  
Oxidising agent.

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## SECTION 11 TOXICOLOGY

פרק 11 רעילות (מידע טוקסיקולוגי)

**Irritancy Studies**

No irritation on the intact skin was observed after the application of Troclosene sodium in the form of undiluted, dry powder for 24 hours. No eye damage or irritation was caused by the daily instillation of a 333ppm solution of Troclosene sodium to each of 5 albino rabbits for 5 days per week for 3 months.

Daily application of 5mls of a 333ml per litre solution, 5 days per week for 3 months to approximately 10% of the body surface of albino rabbits produced no adverse effects.

No eye damage was caused by the daily instillation of 0.1ml suspension of 8% monosodium cyanurate in one eye of each of 5 albino rabbits for 5 days per week for 3 months, to approximately 10% of the body surface of albino rabbits produced no local irritation but slight dilation of Bellini's ducts.

**Toxicology**

**Troclosene** is extremely safe in use. So safe that tablets containing as their active disinfecting ingredient, Troclosene sodium, are used world wide to purify water for drinking purposes. (*Aquatabs* and *Taharmayim*) If however a tablet is swallowed whole, or the prepared solution is drunk by accident, a glass of milk will neutralise any possible unpleasant effects. Risk assessment may therefore be based on the premise that Troclosene is widely used for the purification of drinking water.

Troclosene sodium and its breakdown products were not carcinogenic, teratogenic, mutagenic, fetotoxic or oncogenic in the animals studied. Troclosene sodium has now been in use on open wounds in humans as a registered medicine for several years without incident. Chronic and subchronic studies showed no significant toxicity.

Since cyanurates are rapidly excreted from the body, any adsorption through wounds would not build up in the tissues.

The use of Troclosene sodium (NaDCC) is also listed by the World Health Organisation in their report "*Water Supply Sanitation & Health in Rural Areas*" published in 1991. It is approved by the NSF (National Science Foundation of the USA) for the use in public drinking water (ANSI Standard 60) and also for the same purpose in the United Kingdom.

Aquatabs (known in Israel as Taharmayim) is approved for use world wide for drinking water purification United Nations Common Coding System) UNCCS #856461 and has been in use for many years by western armies, and aid organisations such as the Red Cross, UNICEF, and OXFAM.

Risk assessment for the use of Troclosene sodium therefore best done by examining the toxicity of its breakdown products as follows:

Troclosene -Isocyanurates:

Acute Toxicity LD<sub>50</sub> = 1.67 Gm:Kg in Rats  
 LD<sub>50</sub> = > 2 Gm:Kg in Rabbits  
 LD<sub>50</sub> = 3.57 Gm:Kg in Humans \*

This means that for a 60 Kg adult the LD<sub>50</sub> = 214 Gm or more than 250 tablets of **Klor-De Tablets** would have to be eaten !!

\*Environment Protection Agency (EPA). TSCA Chemical Inventory , USA June 1990, 105810/11/12}

Chronic Toxicity: 333 ppm given orally to dogs and rats for SIX months with no signs of toxicity

Monosodium cyanurate:

Acute Toxicity: LD<sub>50</sub> => 7.5 Gm:Kg in Rats  
 LD<sub>50</sub> = 20 Gm:Kg in Rabbits  
 LD<sub>50</sub> = 21.4Gm:Kg in Cats

Chronic Toxicity 8% cyanurate mixed with the food of dogs was ingested for TWO years with no signs of toxicity

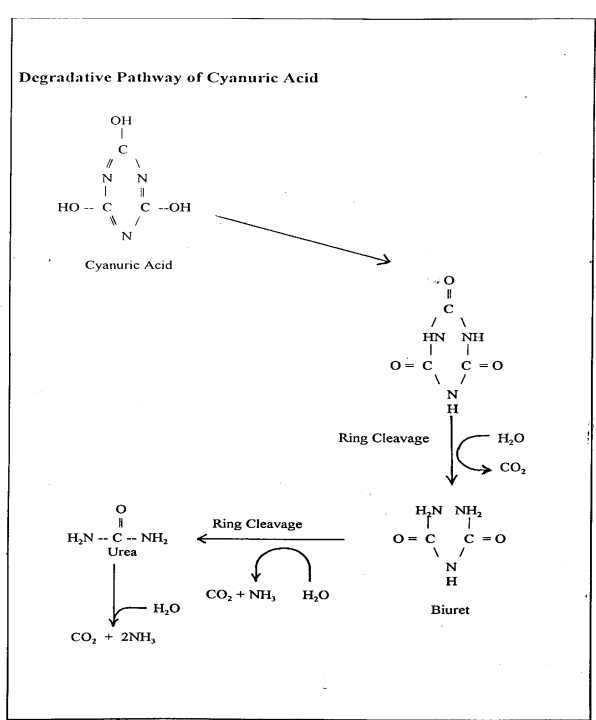
Cyanurates are eliminated unchanged from the human body. The elimination half life is 1.5 to 2 hours. {Allen, 1982}

**ConRaDye Blue** is Ferric Hexacyanoferrate produced in situ and confirmed by UV adsorption to be a single peak Max.abs 694/358 nm. This dye is a permitted colour for Pharmaceutical preparations under US code of Federal regulations Title 21 pt 73 Section 73.2299. It is also allowed for this purpose under Israel Ministry of Health regs (1995). The LD<sub>50</sub> of Ferric Hexacyanoferrate is > 10 g/Kg Per Os.

The risk involved in the use of **Klor-De Tablets** in any setting is therefore negligible.

<b>SECTION 12</b>	<b>פרק 12 מידע סביבתי</b>
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The solution produced by dissolving **Klor-De Tablets** in water is completely biodegradable in the soil, as illustrated in the following diagram. The final breakdown products being ammonia and carbon dioxide.



<b>SECTION 13</b>	<b>פרק 13 דרכי סילוק חומר מסוכן</b>
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If the containers of **Klor-De** are broken and the tablets spilled, they should be swept up in a dry state. Water should not be used to flush them. After gathering up the tablets the area may be flushed with water. Quantities of **Klor-De** Tablets should not be dumped into the sewage system. Tablets to be disposed of should be dissolved in large quantities of water and may then be poured onto earth. The solutions are broken down as shown in section 12.

<b>SECTION 14 Transport</b>	<b>פרק 14 שינוע</b>
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	<p><b>The finished product NOT considered Hazardous</b>  <b>החומר לא נחשב כמסוכן - אין מגבלות בשינוע</b></p>	
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<b>SECTION 15</b>	<b>פרק 15 חקיקה</b>
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	<p>Non applicable</p>	
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<b>SECTION 16</b>	<b>פרק 16 מידע אחר</b>
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	<p><b>Additional health and safety data or usage information on this product will be provided upon request.</b></p> <p>The above information, is intended to give general guidance as to health and safety. Whilst it is correct to the best of our knowledge and belief, no warranty can be given or implied that it will be adequate or applicable for all cases nor that the product will be suitable for any particular purpose since conditions of use are outside our control.</p>	
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