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Mitomycin C 4% in Sodium Chloride

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1. Identification of the Substance and the Manufacturer

1.1. Product identifiers

Prod. name		Mitomycin C 4% in Sodium Chloride	Product Code		-MIT-	
Ingred.	Name	CAS#	ECHA	Concentration	Formula	MW
1	Mitomycin C	50-07-7	200-008-6	4%	C ₁₅ H ₁₈ N ₄ O	334.37
2	Sodium Chloride	7647-14-5	231-598-3	96%	NaCl	58.43
RTECS		-CN0700000-		Mixture?		Mixture
			Vers Date		10 October, 2024	

1.2. Intended uses of the Mixture and uses advised against

1.2.1. Intended use:	1.2.2. Uses advised against:
Research and development. Laboratory reagent. Reference material. Manufacturing of substances. To be used by professionals only	Not a drug, Not a food additive Not to be used in humans or animals.

1.3. Contacts

1.3.1. Details of the supplier of the SDS	
FERMENTEK ltd 4 Yatziv street, POB 47120 Jerusalem 97800, Israel	Tel: +972 2 5853953 Fax: +972 2 5853943 eMail: Fermentek@Fermentek.com Safety@Fermentek.com Website: Fermentek.com
This company is the manufacturer of the product and the supplier of the safety data sheet	
1.3.2. Emergency Telephone number	
For chemical emergency spill, leak, fire, exposure, or accident calls CHEMTREC day or night: Within USA and Canada: 1-800-424-9300. Outside USA and Canada: +1 703-527-3887	





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2. Hazards' identification.

2.1. Classification of the Mixture .

2.1.1. GHS Classification: According to EU Reg. 1272/2008 and US OSHA 1910.1200)

Accute toxicity: Oral	Category 4	H302	Harmful if swallowed
Carcinogenicity	Category 1	H350	May causing cancer
Reproductive toxicity	Category 2	H361d	Suspected of damaging the unborn child
Reproductive toxicity	Category 1	H360F	May damage fertility

2.2. GHS Label elements, including precautionary statements

2.2.1. Pictogram: {  } Signal word: {Danger }

2.2.2. Hazard Statements

H302	Harmful if swallowed
H351	Suspected of causing cancer
H361d	Suspected of damaging the unborn child
H360F	May damage fertility

2.2.3. GHS Precautionary Statements

P203	Obtain, read and follow all safety instructions before use.
P261	Avoid breathing dust or mist.
P264	Wash {hands} thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection

2.2.4. GHS Response Phrases:

H302	Harmful if swallowed
P312	IF SWALLOWED: call a POISON CENTER/doctor IF you feel unwell.
P330	Rinse mouth.
H360F	May damage fertility
H360D	May damage the unborn child
P308+P313	IF exposed or concerned: Get medical advice/attention.

3. Composition/information on ingredients

Mixture	See section 1 for information on ingredients
Substance Name:	Mitomycin C 4% in Sodium Chloride
Classification	Acc O:3 (H302)





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Mixture?	Mixture
4. First Aid Measures.	
4.1. Description of First Aid Measures.	
General advice:	First-aiders need to protect themselves. If medical attention is required, show this safety data sheet to the doctor in attendance.
Eye contact:	Rinse out with plenty of water. Remove contact lenses.
Skin Contact:	In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.
Ingestion:	If swallowed: give water to drink (two glasses at most). Seek medical advice immediately.
Inhalation:	If inhaled, move the person into fresh air.
4.2. Most important symptoms and effects, both acute and delayed	
General symptoms	See section 11
4.3. Indication of any immediate medical attention and special treatment needed	
Note to physicians	No data available
5. Fire-fighting measures.	
5.1. Extinguishing media.	
Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	None known
5.2. Other information	
Hazardous combustion products	Carbon oxides, Nitrogen oxides, Sulfur oxides, Sulfur dihydrogene, Formula see section 1
Advice for firefighters	Wear self-contained breathing apparatus for fire fighting if necessary. Wear protective suit.
6. Accidental release measures	
6.1. Personal precautions, protective equipment, and emergency procedures	
Personal precautions	Use personal protective equipment as required. Keep people away from and upwind of spill/leak.
6.2. Environmental precautions	
Environmental precautions	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.





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6.3. Methods and material for containment and cleaning up

Methods for containment:	Prevent further leakage or spillage if safe to do so. Cover the powder spill with a plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.
Methods for cleaning up:	Clean-up should be dealt with only by qualified personnel familiar with the specific substance. Cover liquid spill with sand, earth or other non-combustible absorbent material (e.g., sand, earth, diatomaceous earth, and vermiculite). Cover the powder spill with a plastic sheet or tarp to minimize spreading. Sweep up and shovel into suitable containers for disposal.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling:	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.
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7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions:	Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Store at -20 °C.
Suitable packaging	Must only be kept in original packaging.
Incompatible materials:	None known based on information available.

8. Exposure Controls/Personal Protection

Attention:

Usually, the product of concern would be present at the intended workplace in miniscule amounts, while surrounded by considerable amounts of other flammable, toxic or otherwise hazardous substances. Therefore, a risk assessment should be performed by the employer/user prior to the use of this product.

The type of protective equipment must be selected based on the amount and concentration of all dangerous materials being used in the workplace.

All recommendations included in this document are advisory in nature

8.1. Control parameters

Control parameters	Components with workplace control parameters
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8.2. Exposure controls

Appropriate engineering controls	Showers, Eyewash stations, Ventilation systems Avoid contact with skin, eyes, and clothing.
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Wash hands before breaks and immediately after handling the product.
Use fume-hood for routine work.

8.3. Personal protective equipment

[PPE=Personal Protection Equipment]

PPE: Respiratory protection	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
PPE: Hand Protection:	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal techniques to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices, and wash and dry hands
PPE: Eye Protection:	Use a face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU)
PPE: Skin and Body Protection:	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

9. Physical and chemical properties

The information given here does not purport specification of warranty of any kind. It is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification.

9.1. Physical/chemical properties

Physical State at room temperature	Solid
Appearance	Powder, White
No further safety relevant data are available	

10. Stability and reactivity

Reactivity:	No information available.
Chemical stability:	Stable under normal conditions.
Conditions to avoid	Heat, flames and sparks. Sunlight.





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Incompatible materials	Strong reducers and oxidizers
Possibility of Hazardous Reactions	None under normal processing
Hazardous combustion products	See section 5

11. Toxicological information

11.1. Information on toxicological effects

To the best of our knowledge, the toxicological effects of this product have not been thoroughly studied yet.

11.1.1. Acute Toxicity

Comment	The information refers to mitomycin C which is the only toxic ingredient in the mixture.
Acute toxicity:	Oral, Mouse, LD50= 23 mg/kg (for pure mitomycin) Estimate of LD50=600mg/kg for mixture. No other acute toxicity available.
Skin corrosion/irritation:	No data available
Serious eye damage/eye irritation:	No data available
Respiratory or skin sensitization/corrosion:	No data available

11.1.2. Chronic toxicity

Chronic toxicity	No data available
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11.1.3. CRM (Carcinogene, Mutagene, Reproductive hazards)

Germ cell mutagenicity:	Mutagenicity demonstrated in many systems
Carcinogenicity:	IARC: possibly carcinogenic to humans (group 2B)
Reproductive toxicity / Teratogenicity:	Damage to male reproductive system reported. Effects on fertility: litter size. Adverse effects on fetus

11.2. Additional information

RTECS number	-CN0700000-
General symptoms	Behavioral - somnolence (general depressed activity) Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Blood – hemolysis; changes in bone marrow; thrombocytopenia Lungs, Thorax, or Respiration - fibrosing alveolitis





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Liver - changes in liver weight

12. Ecological Information

Eco-Toxicity No data available

Other adverse effects No data available

13. Disposal Considerations

13.1. Waste treatment methods

Waste Disposal Dispose of in accordance with local regulations

Contaminated packaging Dispose of as unused product

14. Transport information

14.1. UN Number, Proper Shipping Name, Transport Hazard Class, packing group

UN Number UN 2811-Toxic Solid, Organic, N.O.S. (Mitomycin C 4% in Sodium Chloride)

UN proper shipping name Not classifiable. Not hazardous for transport. (Mitomycin C 4% in Sodium Chloride)

Transport Hazard Class & Packing Group Not classifiable. Not hazardous for transport. (Mitomycin C 4% in Sodium Chloride)

15. Regulatory information

15.1. Safety, health, and environmental regulations/legislation

USA EPA / TSCA This product is not listed on the USA EPA TSCA (it is for research)

EU ECHA Status This Mixture product is Not registered with the EU ECHA,
Active ingredient in the mixture : Mitomycin C EC Number 200-008-6
REACH: PreRegistered.
ANNEX III (criteria for 1 - 10 tonne registered substances): Listed

16. Other information

16.1. Version information

Version date:

16.2. Department issuing this SDS

Quality systems and regulatory affairs

16.3. General Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication.

The information given here is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is **not to be considered a warranty or quality specification.**





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The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless explicitly specified in the text.

16.4. The users'/employers' responsibility:

Usually, the product of concern would be present at the intended workplace in miniscule amounts, while surrounded by considerable amounts of other flammable, toxic or otherwise hazardous substances. Therefore, a risk assessment should be performed by the employer/user prior to the use of this product.

The type of protective equipment must be selected based on the amount and concentration of all dangerous materials being used in the workplace.

All recommendations included in this document are advisory in nature.

16.5. No © copyright



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16.6. End of SDS





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Appendix A : Abbreviations and acronyms:

Acute Tox.:	Acute toxicity
CAS:	Chemical Abstracts Service
Comptox	CompTox Chemicals Dashboard Resource Hub (EPA)
DOT:	US Department of Transportation
ECHA	European Chemicals Agency
EINECS:	European Inventory of Existing Commercial Chemical Substances
EPA	United States Environmental Protection Agency
Eye Dam.:	Serious eye damage/eye irritation
HSDB	Hazardous Substances Data Bank
HMIS:	Hazardous Materials Identification System (USA)
IATA:	International Air Transport Association
IMDG:	International Maritime Code for Dangerous Goods
LC50:	Lethal concentration, Median
LD50:	Lethal dose, Median
LDL0	Letal dose, least published
NDG	Not dangerous goods (for transport)
NFPA:	National Fire Protection Association USA
NIOSH:	National Institute for Occupational Safety
OSHA:	Occupational Safety & Health
PBT:	Persistent, Bioaccumulative, and Toxic
PEL:	Permissible Exposure Limit
REL:	Recommended Exposure Limit
Repr.:	Reproductive toxicity
RTECS:	Registry of Toxic Effects of Chemical Substances
Skin Irrit:	Skin corrosion/irritation
STOT/SE	Specific target organ toxicity/Single exposure
STOT/RE	Specific target organ toxicity/Repeated exposure
T3DB	Toxin and Toxin Target Database
TDL0	Toxic dose, least published





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Appendix B : Toxicity conversion to regulatory categories

Source: <https://www.ilo.org/legacy/english/protection/safework/ghs/ghsfinal/ghsc05.pdf>

Data in mg/kg body weight ; LD50/oral/Mouse or Rat; rats usually are more susceptible.

If no oral data available but subcutaneous/IV is, you can guess oral by multiplying IP by 10 or IV by 20.

Exposure	CAT 1	CAT 2 LD50/oral/mouse	CAT 3 LD50/oral/mouse	CAT 4 LD50/oral/mouse
Oral	<5	5-50	50-300	300-2000
Dermal	<50	5-200	200-1000	1000-2000
Dust/Mist mg/L (timing?)	<0.2	0.2-2	2-4	
Packing Group	1	2	3	NDG

