




Sterling Chemical Malta LTD

SAFETY INSTRUCTION: MANAGEMENT OF CARCINOGENS SUBSTANCES

REVISION HISTORI

Revision Date	Revision number	Sections Affected	Change description
13/09/2013	00	--	First emission document

Instruction Number: MIOS_4.4.6-D2	Edited by: Safety Assistant	Verified and approved by: Safety Responsible
Page 1 of 8		

	Sterling Chemical Malta LTD	SAFETY INSTRUCTION	Instruction Number MIOS_4.4.6-D2
Date issue: 13.09.2013	MANAGEMENT OF CARCINOGENS SUBSTANCES		Revision 00
			Page 2 of 8

1. PURPOSE

This procedure indicates the precautions in the use of substances that are known carcinogens and / or mutagenic (or are suspected to be), in compliance with Legal Notice 122 of 2003.

2. FIELD OF APPLICATION

It applies to the entire company Sterling Chemical Malta Ltd.

3. BASIC DEFINITIONS

We define carcinogenic chemical compounds, for protracted action in the human body, that can cause cancer in exposed subjects, even after many years since the cessation of exposure.

We define mutagenic substances, that can induce mutations in living cells, where the term mutation means that a cell no longer has the same genetic composition of the other cells of the organism

1) **Cancerogen:**


- a) A substances which meets the criteria for classification as a category 1 or 2 carcinogen set out in Annex VI of Directive 93/72/EEC
- b) A preparation composed of one or more substances referred to in a) paragraph where the concentration of one or more of the individual substances meets the requirements of a preparation as category 1 or 2 carcirogen set out either:
 - In Annex I to Directive 93/72/EEC, or
 - In Annex I to Directive 88/379/EEC where the substances do not appear in Annex I to Directive 93/72/EEC or appear in it without concentration limits;
- c) A substance, preparation or process referred to in Annex I as well as a substance or preparation released by a process referred to in Annex I.

2) **Mutagen:**

- a) A substance with meets the criteria for classification as category 1 or 2 mutagen set out in Annex VI to Directive 93/72/EEC;
- b) A preparation composed of one or more substances referred to in paragraph a) where the concentration of one or more of the individual substances meets the requirements fo concentration limits for the classification of a preparation of a preparation as a category 1 or 2 mutagen set out in either:
 - Annex I to Directive 93/72/EEC, or
 - Annex I to Directive 88/379/EEC where the substance or substances do not appear in Annex I to Directive 93/72/EEC or appear un it without concentration limits.

EC CLASSIFICATION

According to the classification of the EC (Directive 93/72/EEC), such substances are divided into 3 categories:

 Sterling Chemical Malta LTD	SAFETY INSTRUCTION	Instruction Number MIOS_4.4.6-D2
Date issue: 13.09.2013	MANAGEMENT OF CARCINOGENS SUBSTANCES	Revision 00
		Page 3 of 8

- **Category 1**
- **Category 2**
- **Category 3**

The substances in categories 1 and 2 must be marked with the initials H350 "may cause cancer" or "may cause cancer by inhalation", while those of Class 3 must be marked with the initials H351 "Suspected of causing cancer ". Moreover, substances of categories 1 and 2 are classified for the purpose of labeling with the least toxicity pictogram, and those of category 3 with the pictogram harmful substance.

According to the classification of the EC (Directive 93/72/EEC) mutagenic substances that have relevance to the current legislation are divided into two categories:

- **Category 1**
- **Category 2**

IARC CLASSIFICATION

The International Agency for Research on Cancer (IARC) identifies 4 categories of carcinogenesis divided as follows:

- Group 1 - "Human Carcinogens"
- Group 2 . - Subgroup 2A - "Probable human carcinogens" - Subgroup 2B - "Suspected human carcinogens"
- Group 3 - "substances not classifiable as carcinogenic to humans"
- Group 4 – “ Not carcinogenic to humans".

The IARC classification of carcinogens is as follows:


They are considered carcinogenic especially agents belonging to groups 1 and 2A.

4. REGISTER OF CARCINOGEN AND MUTAGENIC USE

The "**Register of use of carcinogens and mutagens**" MM_4.4.6-D1 is a form that the Company has established to monitor the use of carcinogens and mutagens within the departments. In it, each operator using a human carcinogen and / or mutagen is required to indicate important information about: date of use, name of substance, quantity used, time of use.

5. RESPONSIBILITIES

The heads of department control and require that staff follow the instructions received, provide the staff the Personal Protective Equipment necessary, propose any amendment to this procedure.

 Sterling Chemical Malta LTD	SAFETY INSTRUCTION	Instruction Number MIOS_4.4.6-D2
Date issue: 13.09.2013	MANAGEMENT OF CARCINOGENS SUBSTANCES	Revision 00
		Page 4 of 8

The Safety Responsible has the responsibility to conduct audits / inspections at regular intervals in the laboratory and in the production department to verify compliance with procedures. The staff must comply with the provisions of the Procedure and other related documents and present to manager any health and safety issues.

6. PROCEDURE FOR THE NEW AGENT SUPPLY

The department head must always perform a check on the possibility of replacing a carcinogenic mutagen reagent with an alternative less dangerous, so before purchasing a new carcinogen-mutagen is requested that the Head of Department makes a preliminary analysis of risk through the **Change Proposal MM_4.3.1-A**.

It is important in particular because it specifies the use of the substance and because it cannot be replaced with another reagent less dangerous.

It is requested that before the purchase department obtains authorization from the Safety Responsible and Head of Department. After receiving the approval, the Head of Department, together with the Safety Responsible provides training for people exposed to the use of the carcinogen-mutagen, illustrating the characteristics of the agent in its MSDS.

7. PROCEDURE FOR NOTIFICATION OF NEW EXPOSED


Head of Department must notify to EHS Office a new exposed by the **Change Proposal MM_4.3.1-A**. To the proposal the Head of Department attached the following informations:

- Identification, physical characteristic, danger of the substance;
- Worker exposed.

Approved the change, Head of Department and Safety Responsible provide to the training of new exposed.

8. USE OF CARCINOGENS AGENTS IN CONTROL QUALITY LAB

- Use of Carcinogens-mutagens must be done by expert personnel following the procedures;
- Use of Carcinogens-mutagens must be done under adequate intake (eg, fume hood) and / or providing a "closed" system that does not produce emissions of the carcinogen-mutagen in the environment. Plan and supervise the activities so that there is no emission of carcinogens and mutagens in the air;
- Personnel should wear PPE provided and follow the procedures; - Use the minimum amount of Carcinogens-Mutagens;
- Minimize the number of people involved and the quantity in use of Carcinogens-Mutagens;

	Sterling Chemical Malta LTD	SAFETY INSTRUCTION	Instruction Number MIOS_4.4.6-D2
Date issue: 13.09.2013	MANAGEMENT OF CARCINOGENS SUBSTANCES	Revision 00	
		Page 5 of 8	

Storage: Store the Carcinogens - Mutagens in the warehouse storage in the dedicated container. The agents must be closed by a double envelope.

Specimen Collection and Handling of Carcinogenic - Mutagenic: Ensure the proper functioning of fume hood, warn other people of use Mutagen-Carcinogen. At the opening of the cabinet of storage, check the integrity, closing and cleaning of the container of the reagent, prior to manipulate it. Avoid, where possible, to perform these operations during the period of maximum of local crowding. Do not perform these operations during the presence of any external operators and contractors (or visitors) in the lab.

Handling: Prior to the opening of the container control the operation of fume hoods. Always work under a hood intake.

Cleaning: To avoid indirect contamination to other personnel, special care should be placed in the conditioning of wastes and contaminated PPE used. The work area must be kept clean and tidy and with the least amount of material necessary to the experimental work. The contaminated area must be cleaned immediately, by the appropriate personnel.

PPE to be used: Laboratory personnel during the handling of mutagenic-carcinogens must wear:

- Lab coat with dedicated top coat;
- Safety goggles to EN166;
- Gloves;
- Disposable shoe covers;
- Headphone;
- Semi face mask complete with filters polyvalent ABEK1 P3.


At the end of every transaction in the manipulation of Carcinogenic-mutagenic substances in particular, gloves, and disposable clothing should be discarded into the waste container. The operator provides also to the washing of hands.

Proper Disposal: The disposal of chemical residues of carcinogenic or mutagenic nature must be made separately with respect to the disposal of other wastes. Specifically, the analyst should follow this practice:

I. The chemical will remain in its container and for any reason must not be mixed with other waste solids or liquids in the laboratory.

II. Having determined without use of the product he should contact EHS Office that will label the refusal by putting the following information:

- EWC code;
- Name of the refusal;
- Weight;
- Date of its production or identification as waste; the label affixed to the product must not cover the raw material so as to give more objective evidence of the risk phrases and safety;

	Sterling Chemical Malta LTD	SAFETY INSTRUCTION	Instruction Number MIOS_4.4.6-D2
Date issue: 13.09.2013	MANAGEMENT OF CARCINOGENS SUBSTANCES		Revision 00
			Page 6 of 8

III. The operator collects the waste and disposes the waste in temporary storage in a suitable container;

IV. The waste responsible contact transport and disposable company to manage the waste.

This procedure must be followed also for container and packaging of carcinogens substances.

9. USE OF CARCINOGENS AGENTS IN WAREHOUSE DEPARTMENT

- Use of Carinogens-mutagens must be done by expert personnel following the procedures;
- Use of Carcinogens-mutagens must be done under adequate intake (eg, fume hood) and / or providing a "closed" system that does not produce emissions of the carcinogen-mutagen in the environment. Plan and supervise the activities so that there is no emission of carcinogens and mutagens in the air;
- Personnel should wear PPE provided and follow the procedures; - Use the minimum amount of Carcinogens-Mutagens;
- Minimize the number of people involved and the quantity in use of Carcinogens-Mutagens;

Storage: Store the Carcinogens - Mutagens in the warehouse storage in the dedicated container. The agents must be closed by a double envelope.


Specimen Collection and Handling of Carcinogenic - Mutagenic: warn other people of use Mutagen-Carcinogen. Check the integrity, closing and cleaning of the container of the reagent, prior to manipulate it.

Handling: all the operations must be done in the sampling room under the fume hood. Ensure the proper functioning of fume hood, warn other people of use Mutagen-Carcinogen. At the opening of the cabinet of storage, check the integrity, closing and cleaning of the container of the reagent, prior to manipulate it. Avoid, where possible, to perform these operations during the period of maximum of local crowding. Do not perform these operations during the presence of any external operators and contractors (or visitors). At the end of the splitting insert the remaining product in the container

Cleaning: To avoid indirect contamination to other personnel, special care should be placed in the conditioning of wastes and contaminated PPE used. The work area must be kept clean and tidy and with the least amount of material necessary to the experimental work. The contaminated area must be cleaned immediately, by the appropriate personnel.

PPE to be used: warehouse operators during the handling of mutagenic-carcinogens must wear:

- disposable complete coverall;
- Gloves;
- Disposable shoe covers;
- Hairnets;
- Whole face mask complete with filters polyvalent ABEK2 P3.

	Sterling Chemical Malta LTD	SAFETY INSTRUCTION	Instruction Number MIOS_4.4.6-D2
Date issue: 13.09.2013	MANAGEMENT OF CARCINOGENS SUBSTANCES		Revision 00
			Page 7 of 8

At the end of every transaction in the manipulation of Carcinogenic-mutagenic substances in particular, gloves, and disposable clothing should be discarded into the waste container. The operator provides also to the washing of hands.

Proper Disposal: The disposal of chemical residues of carcinogenic or mutagenic nature must be made separately with respect to the disposal of other wastes. Specifically, the analyst should follow this practice:

I. The chemical will remain in its container and for any reason must not be mixed with other waste solids or liquids in the laboratory.

II. Having determined without use of the product he should contact EHS Office that will label the refusal by putting the following information:

- EWC code;
- Name of the refusal;
- Weight;
- Date of its production or identification as waste; the label affixed to the product must not cover the raw material so as to give more objective evidence of the risk phrases and safety;

III. The operator collects the waste and disposes the waste in temporary storage in a suitable container;

IV. The waste responsible contact transport and disposable company to manage the waste.


This procedure must be followed also for container and packaging of carcinogens substances.

10. ISTRUZIONE OPERATIVA PER L'UTILIZZO DEGLI AGENTI CANCEROGENI-MUTAGENI NEL REPARTO PRODUZIONE

- Use of Carinogens-mutagens must be done by expert personnel following the procedures;
- Use of Carcinogens-mutagens must be done under adequate intake (eg, fume hood) and / or providing a "closed" system that does not produce emissions of the carcinogen-mutagen in the environment. Plan and supervise the activities so that there is no emission of carcinogens and mutagens in the air;
- Personnel should wear PPE provided and follow the procedures; - Use the minimum amount of Carcinogens-Mutagens;
- Minimize the number of people involved and the quantity in use of Carcinogens-Mutagens;

Storage: Store the Carcinogens - Mutagens in the warehouse storage in the dedicated container. The agents must be closed by a double envelope.

Specimen Collection and Handling of Carcinogenic - Mutagenic: warn other people of use Mutagen-Carcinogen. Check the integrity, closing and cleaning of the container of the reagent, prior to manipulate it.

	Sterling Chemical Malta LTD	SAFETY INSTRUCTION	Instruction Number MIOS_4.4.6-D2
Date issue: 13.09.2013	MANAGEMENT OF CARCINOGENS SUBSTANCES	Revision 00	
		Page 8 of 8	

Handling: the loading of the substance on the reactor must be done through the hatch. Check the function of the suction port, warn other people of use Mutagen-Carcinogen. At the opening of the cabinet of storage, check the integrity, closing and cleaning of the container of the reagent, prior to manipulate it. Avoid, where possible, to perform these operations during the period of maximum of local crowding. Do not perform these operations during the presence of any external operators and contractors (or visitors). At the end of the splitting insert the remaining product in the container

Cleaning: To avoid indirect contamination to other personnel, special care should be placed in the conditioning of wastes and contaminated PPE used. The work area must be kept clean and tidy and with the least amount of material necessary to the experimental work. The contaminated area must be cleaned immediately, by the appropriate personnel.

PPE to be used: warehouse operators during the handling of mutagenic-carcinogens must wear:

- disposable complete overalls;
- Gloves;
- Disposable shoe covers;
- Hairnets;
- Whole face mask complete with filters polyvalent ABEK2 P3.

At the end of every transaction in the manipulation of Carcinogenic-mutagenic substances in particular, gloves, and disposable clothing should be discarded into the waste container. The operator provides also to the washing of hands.

Proper Disposal: The disposal of chemical residues of carcinogenic or mutagenic nature must be made separately with respect to the disposal of other wastes. Specifically, the analyst should follow this practice:

I. The chemical will remain in its container and for any reason must not be mixed with other waste solids or liquids in the laboratory.

II. Having determined without use of the product he should contact EHS Office that will label the refusal by putting the following information:

- EWC code;
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III. The operator collects the waste and disposes the waste in temporary storage in a suitable container;

IV. The waste responsible contact transport and disposable company to manage the waste.

This procedure must be followed also for container and packaging of carcinogens substances.