

1. Identification

Product identifier	Myleran 2mg Tablets (Busulfan)
Other means of identification	Not available.
Synonyms	Myleran, Busulfan, Busulphan
Recommended use	Medicinal product.
Recommended restrictions	None known.

Manufacturer / Importer / Supplier / Distributor information

Company name	Aspen Europe GmbH
Address	Industriestrasse- 32-36 D-23843 Bad Oldesloe Germany
Telephone	(+) 44 1748 828 391
E-mail	SDSRequest@aspengl.com

Emergency phone number	(USA, Canada, Mexico)	1.866.519.4752
	(Americas)	(+) 1 760 476 3962
	Access code	333974

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, inhalation	Category 4
	Sensitization, skin	Category 1
	Germ cell mutagenicity	Category 1B
	Carcinogenicity	Category 1B
	Reproductive toxicity	Category 1B
OSHA defined hazards	Not classified.	

Label elements



Signal word Danger

Hazard statement May cause genetic defects. May cause cancer. May cause an allergic skin reaction. May damage fertility. May damage the unborn child. Harmful if inhaled.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. Avoid breathing dust. Use only outdoors or in a well-ventilated area.

Response If exposed or concerned: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) Not classified.

Supplemental information

Not applicable.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Busulphan	55-98-1	0.56-2

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation	Not likely, due to the form of the product.
Skin contact	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. If skin irritation or rash occurs: Get medical advice/attention. For minor skin contact, avoid spreading material on unaffected skin.
Eye contact	Flush thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth thoroughly with water and give large amounts of water to people not unconscious. Do not induce vomiting without advice from medical personnel.
Most important symptoms/effects, acute and delayed	May cause allergic skin reaction.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. In case of shortness of breath, give oxygen. Keep victim warm. Keep victim under observation. Symptoms may be delayed. Medical treatment in cases of overexposure should be treated as an overdose of a cytotoxic agent. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. IF exposed or concerned: Get medical advice/attention.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry powder.
Unsuitable extinguishing media	Carbon dioxide extinguishers may be ineffective. Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Move containers from fire area if you can do so without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see Section 8 of the SDS.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Containers with collected spillage must be properly labelled with correct contents and hazard symbol.
Environmental precautions	Never return spills in original containers for re-use. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not taste or swallow. Avoid breathing dust. Avoid contact with skin. Pregnant or breastfeeding women must not handle this product. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Strict control of access to the working area is essential. Only trained personnel should enter the area during operations. Adopt procedures to prevent contamination of working materials and adjacent areas. This product is listed by US NIOSH as a hazardous drug when handled in health care settings. For additional information about the NIOSH hazardous drugs programme and recommendations for preventing exposure see US NIOSH publication "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings." Avoid breaking or crushing tablets.
Conditions for safe storage, including any incompatibilities	Store in a closed container away from incompatible materials. Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls It is strongly advised that dedicated areas and containment, such as glove boxes, isolators, and enclosed material transfer systems be used to prevent personnel exposure and spread of contamination. Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.

Individual protection measures, such as personal protective equipment

Eye/face protection Risk of contact: Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear protective gloves. Suitable gloves can be recommended by the glove supplier. Frequent change is advisable.

Other Wear suitable protective clothing.

Respiratory protection When isolation is not possible, respiratory protective equipment (RPE) should be combined with applicable protective equipment.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace. Observe any medical surveillance requirements.

9. Physical and chemical properties

Appearance White, film-coated, round, biconvex tablets containing 2 mg busulfan in amber glass bottles with child-resistant closures. One side is imprinted with "GX EF3" and the other side is imprinted with an "M".

Physical state Solid.

Form Tablet.

Color White.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not applicable.

Oxidizing properties Not applicable.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Adverse effects may occur after swallowing.
Inhalation	Harmful if inhaled.
Skin contact	May cause skin irritation. May cause allergic skin reaction.
Eye contact	Product dust or powder may cause mechanical eye irritation.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with skin and eyes may cause irritation. May cause allergic skin reaction.

Information on toxicological effects

Acute toxicity	Harmful if inhaled.
Skin corrosion/irritation	Not classified.
Serious eye damage/eye irritation	Not classified.
Respiratory sensitization	Not classified.
Skin sensitization	May cause allergic skin reaction.
Germ cell mutagenicity	May cause genetic defects.
Carcinogenicity	May cause cancer.

IARC Monographs. Overall Evaluation of Carcinogenicity

Busulphan (CAS 55-98-1) 1 Carcinogenic to humans.

NTP Report on Carcinogens

Busulphan (CAS 55-98-1) Known To Be Human Carcinogen.

Reproductive toxicity	May damage the unborn child.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; gastro-intestinal tract; liver.
Aspiration hazard	Not classified.
Chronic effects	Prolonged exposure may cause chronic effects. May cause damage to the following organs through prolonged or repeated exposure: Bone marrow. Liver. Blood.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
Busulphan (CAS 55-98-1)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50 Daphnia magna	> 10 mg/l, 48 hours

Persistence and degradability This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water.

Hydrolysis

Half-life (Hydrolysis)

Myleran 2mg Tablets (Busulfan) (CAS Mixture) < 24 hours, Measured

Bioaccumulative potential	The product is not expected to bioaccumulate.
Mobility in soil	The product is soluble in water.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical Yes

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Busulphan (CAS 55-98-1)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Busulphan (CAS 55-98-1)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

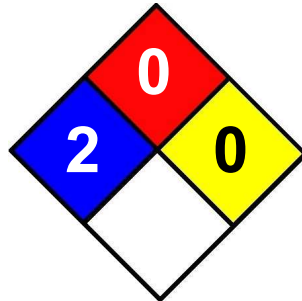
WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Busulphan (CAS 55-98-1)

16. Other information, including date of preparation or last revision

Issue date 10-July-2013
Revision date -
Version # 01
NFPA Ratings



List of abbreviations

IATA: International Air Transport Association.
IMDG: International Maritime Dangerous Goods.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
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.

LD50: Lethal Dose, 50%.

References

GSK Myleran SDS Version 15 17 September 2008.

Disclaimer

While the information and recommendations contained in this safety data sheet are believed to be correct at the time of issue, liability for its accuracy, adequacy or completeness is excluded to the maximum extent permissible by law and no express or implied warranty is given. This exclusion extends to liability for any statement, opinion or conclusion contained in or any omission from this safety data sheet (including its annexes and references) and for any other related written or oral communication. No representations or warranties are made for these statements, opinions or conclusions and the user must determine the correct and proper use of the material described in this safety data sheet.