

Information about Compilation of Safety Data Sheets

Product: HistoMark® X-Gal Substrate Set
Company: SeraCare Life Sciences
Article number: 5520-0022

All components of the aforementioned kit had been classified according to Regulation (EC) No. 1907/2006 (REACH) and to Regulation (EC) No. 1272/2008 (GHS/CLP).

For the kit component X-Gal Substrate Solution (article number 71-00-56), a Safety Data Sheet had been compiled (enclosure).

For the other kit component Iron Buffer Reagent (article number 71-00-55), no Safety Data Sheet is required after classifications according to the Regulation (EC) No. 1907/2006 (REACH) and the Regulation (EC) No. 1272/2008 (GHS/CLP).

When handling the kit components, the general and specific safety precautions for laboratories and the corresponding directives have to be followed.

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medac

Product Safety
Safety Health Environment
Phone: +49 (0)4103 8006 0
Fax: +49 (0)4103 8006 100
E-mail: productsafety@medac.de

Theaterstrasse 6
22880 Wedel
Germany

Attachment

Geschäftsführer:
Jens Denker
Dr. Rainer Dickhardt
Jörg Hans
Dr. Ulrich Kosciessa
Nikolaus Graf Stolberg
Heiner Will

Registergericht:
Pinneberg HRB 12042 PI

Umsatzsteuer ID:
DE 118579535

**Safety data sheet
according to 1907/2006/EC, Article 31**

Printing date 19.12.2017

Version number 1

Revision: 19.12.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** X-Gal Substrate Solution**Article number:** 71-00-56**Registration number**

This product is a mixture (see chapter 3). Registration number(s) is/are not available for this substance/these substances as the substance(s) or its/their use are exempted from registration according to Article 2 REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

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

Relevant identified uses:

RUO (Research Use Only).

Uses advised against:

For in vitro diagnosis.

Sector of Use SU24 Scientific research and development**Product category** PC21 Laboratory chemicals**Process category** PROC15 Use as laboratory reagent**Application of the substance / the mixture** Immunochemical reagent for detection / auxiliary reagent**1.3 Details of the supplier of the safety data sheet****Manufacturer/Distributor:**

Manufacturer:

SeraCare Life Sciences (KPL)

910 Clopper Road

Gaithersburgh, Maryland 20878, USA

Distributor:

medac GmbH

Theaterstrasse 6

22880 Wedel, Germany

phone: +49 4103 8006-0

Informing department:

Product Safety

productsafety@medac.de

1.4 Emergency telephone number:

Giftinformationszentrum-Nord, Phone: ++49 551 19 240 (service in German and English, 24 hours permanently accessible).

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

The product is classified according to CLP regulation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Repr. 1B H360D May damage the unborn child.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labeled in accordance with Regulation (EC) No 1272/2008 (GHS/CLP).

Hazard pictograms

GHS07 GHS08

Signal word Danger**Hazard-determining components of labelling:**

N,N-dimethylformamide

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Hazard statements

H319 Causes serious eye irritation.
H360D May damage the unborn child.

Precautionary statements

P201 Obtain special instructions before use.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.

Additional information:

Restricted to professional users.

Reduced labelling (<125 ml):

Labelling of packages where the contents do not exceed 125 ml**Hazard pictograms**

GHS07 GHS08

Signal word Danger**Hazard-determining components of labelling:**

N,N-dimethylformamide

Hazard statements

H360D May damage the unborn child.

Precautionary statements

P201 Obtain special instructions before use.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.

2.3 Other hazards**Results of PBT and vPvB assessment****PBT:** Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.**vPvB:** Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: Composition/information on ingredients

3.1. Chemical characterisation: substances Not applicable. Product is a mixture.**3.2 Chemical characterisation: Mixtures****Description:** Immunochemical reagent / auxiliary reagent**Dangerous components:**

CAS: 68-12-2	N,N-dimethylformamide	≤10%
EINECS: 200-679-5	Flam. Liq. 3, H226	
Index number: 616-001-00-X	Repr. 1B, H360D	
RTECS: LQ 2100000	Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319	

SVHC

Not applicable.

68-12-2 | N,N-dimethylformamide

Additional information For the wording of the listed H-phrases please refer to Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures**General information** First aider: Take care of self-protection.

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After inhalation

Supply fresh air.

In case of symptoms call a physician.

After skin contact

Instantly remove contaminated clothes.

Wash with copious amounts of water.

Call in physician.

After eye contact

Rinse eyes cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

Instantly consult ophthalmologist.

After swallowing

Wash out mouth with copious amounts of water.

Let drink water (2 glasses maximum).

Call doctor.

4.2 Most important symptoms and effects, both acute and delayed

Gastric or intestinal trouble

Irritant effects.

Information for doctor Show Safety Data Sheet.**Danger** No further relevant information available.**4.3 Indication of any immediate medical attention and special treatment needed**

Treatment according to symptoms.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing agents** Product itself does not burn. Use fire fighting measures that suit the environment.**For safety reasons unsuitable extinguishing agents** For this mixture no limitations of extinguishing agents are given.**5.2 Special hazards arising from the substance or mixture**

Formation of toxic gases is possible during heating or in case of fire.

In the event of fire may develop:

Nitrogen oxides (NO_x)

Carbon monoxide (CO)

Carbon dioxide (CO₂)**5.3 Advice for firefighters****Protective equipment:**

Stay in the danger area only with self-contained breathing apparatus.

Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Additional information

Precipitate gases/fumes/mists with water spray jet.

Collect contaminated fire fighting water separately. It must not enter drains.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Advice for non-emergency personnel:

Provide sufficient ventilation.

Advice for emergency responders: Protective equipment: see Section 8.

6.2 Environmental precautions: Do not empty into drains.**6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Afterwards clean with water and cleansing agent.

Dispose of contaminated material as waste according to Section 13.

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6.4 Reference to other sections

See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Open and handle container with care.
Ensure good ventilation/exhaustion at the workplace.

Information about protection against explosions and fires: No danger of explosion.**7.2 Conditions for safe storage, including any incompatibilities** No further relevant information available.**Storage****Requirements to be met by storerooms and containers:** Store at +2 °C to +8 °C.**Information about storage in one common storage facility:** Store separately from strong oxidants and halogens.**Further information about storage conditions:**

Store in a locked cabinet or with access restricted to technical experts or their assistants.

Storage class Please see the respective national guidelines.**7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see Section 7.**8.1 Control parameters****Components with critical values that require monitoring at the workplace:****68-12-2 N,N-dimethylformamide**

WEL	Short-term value: 30 mg/m ³ , 10 ppm
	Long-term value: 15 mg/m ³ , 5 ppm
Sk	

DNELs No further relevant information available.**PNECs** No further relevant information available.

CAS No.	Designation of material	%	Type	Value	Unit
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Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable.**Additional information:** The official lists that were valid during the compilation were used as basis.**8.2 Exposure controls**

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See Section 7.

Personal protective equipment**General protective and hygienic measures**

The usual precautionary measures should be adhered to in handling the chemicals.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Do not eat or drink while working.

Keep away from food and beverages.

Wash hands during breaks and at the end of the work.

Breathing equipment: No special precautions are necessary if handled correctly.**Protection of hands:**

Protective gloves (AQL 1.5).

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The breakthrough times stated below base on laboratory test methods which cannot fully simulate working conditions. It is the responsibility of the enduser to choose the appropriate gloves for his application. If working with substances or mixtures harmful in contact with skin, check the gloves beforehand for holes and fissures.

Material of gloves

Nitrile rubber, NBR

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Natural rubber, NR

Thickness 0.11 mm.

Product quality must comply with standard EN 374.

Penetration time of glove material Penetration time > 120 min.**For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**

Product has not been designed for permanent contact.

For the permanent contact gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR

Natural rubber, NR

Layer thickness: 0,4 mm.

Penetration time > 120 min.

Eye protection: Safety glasses (standard EN 166).**Body protection:** Protective work clothing.**Limitation and supervision of exposure into the environment** Do not empty into drains.**Risk management measures** Void.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	liquid
Colour:	Colourless
Smell:	slightly amine-like
Odour threshold:	No information available.

Important information on protection of health and environment, and on safety.

No further relevant information available.

pH-value:	No information available.
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Change in condition	Not applicable.
Melting point/freezing point:	No information available. Not determined.

Flash point:	Not applicable.
Inflammability (solid, gaseous)	Not applicable.
Ignition temperature:	No information available.
Decomposition temperature:	No information available.
Self-inflammability:	Not self-inflammable.
Explosive properties:	Not explosive.
Critical values for explosion:	
Lower:	Not applicable.
Upper:	Not applicable.
Oxidising properties	No information available.
Density	No information available.
Relative density	No information available.
Vapour density	No information available.
Evaporation rate	No information available.
Solubility in / Miscibility with	
Water:	Miscible
Partition coefficient: n-octanol/water:	No information available.
Viscosity:	
dynamic:	No information available.
kinematic:	No information available.

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Solvent content:**Organic solvents:** $\geq 90 \%$ **Water:** 0% **Solids content:** ≤ 10 **9.2 Other information**

No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity For this mixture no relevant information available.**10.2 Chemical stability** The product is chemically stable under the indicated storage conditions.**Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

Conditions to be avoided:

Heating.

Light.

10.3 Possibility of hazardous reactions For these concentrations no relevant information available.**10.4 Conditions to avoid:** No further relevant information available.**10.5 Incompatible materials:** For these concentrations no further relevant information available.**10.6 Hazardous decomposition products:**

Dimethylamine.

Formaldehyde

In case of burning of larger amounts: See Section 5.

Additional information: No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects Data on the toxicity of this mixture are not available.**Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC50 values that are relevant for classification:****68-12-2 N,N-dimethylformamide**

Oral	LD50	2800 mg/kg (rat)
Dermal	LD50	1500 mg/kg (rabbit)
Inhalative	LC50/4 h	9-15 mg/l (rat)

Specific symptoms in biological assay: No further relevant information available.**Primary irritant effect:****Skin corrosion/irritation** Irritations possible.**Serious eye damage/irritation**

Strong irritant effects.

Causes serious eye irritation.

after swallowing: Mucosal irritations in mouth, pharynx and oesophagus possible.**after inhalation:** Irritations possible.**Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.**Other information (about experimental toxicology):** No further relevant information available.**Subacute to chronic toxicity:** Danger of cutaneous absorption.**Additional toxicological information:** No further relevant information available.**Toxicokinetics, metabolism and distribution** No relevant information available.**Acute effects (acute toxicity, irritation and corrosivity)** No acute toxicity information available for this product.**Sensitisation** No sensitising effect known.**Repeated dose toxicity** Hepatopathy.**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)** Repr. Cat. B**Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.

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Reproductive toxicity

May damage the unborn child.

STOT-single exposure Based on available data, the classification criteria are not met.**STOT-repeated exposure** Based on available data, the classification criteria are not met.**Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity**Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** Readily biodegradable (OECD Test Guideline 301D).**Other information:** No further relevant information available.**Behaviour in environmental systems:****Components:** No relevant information available.**12.3 Bioaccumulative potential**

log Pow <1

Bioaccumulation is not to be expected.

12.4 Mobility in soil High mobility (source: ECHA).**Ecotoxicological effects:****Remark:**

Fischtoxizität:

LC₅₀: Lepomis macrochirus: 6300 mg/l / 96h.LC₅₀: Onchorhynchus mykiss: 9800 mg/l / 96h.LC₅₀: Plimephales promelas: 10600 mg/l / 96h.

Daphnientoxizität:

LC₅₀: Daphnia magna: 15700 mg/l / 48h.

Algentoxizität:

LC₅₀: Desmodesmus subspicatus IC50 > 500 mg/l / 96h.**Additional ecological information:****General notes:** Void.**12.5 Results of PBT and vPvB assessment****PBT:** PBT assessment not available as chemical safety assessment not required/not conducted.**vPvB:** vPvB assessment not available as chemical safety assessment not required/not conducted.**12.6 Other adverse effects** No relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product residues have to be disposed of according to the Waste Framework Directive as well as national and regional regulations in each of the latest versions.

Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Uncleaned packagings:**Recommendation:** Uncleaned packagings have to be disposed of in the same manner as the product residues.

SECTION 14: Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA

-

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA

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14.3 Transport hazard class(es)ADR, ADN, IMDG, IATA
Class

-

14.4 Packing group

ADR, IMDG, IATA

-

14.5 Environmental hazards:

Marine pollutant:

No

14.6 Special precautions for user

Not applicable.

**14.7 Transport in bulk according to Annex II of Marpol
and the IBC Code**

Not applicable.

Transport/Additional information:Not classified as dangerous in the meaning of transport
regulations as issued in the latest version.**UN "Model Regulation":**

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SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Labelling according to Regulation (EC) No 1272/2008**

Hazard pictograms See Section 2.

Signal word See Section 2.

Hazard-determining components of labelling: See Section 2.

Hazard statements See Section 2.

Precautionary statements See Section 2.

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

National regulations**Information about limitation of use:**

Take note of the directive on the protection of young people at work in the latest version.

Take note of the directive on the safety and health at work for pregnant and breast feeding mothers and workers of
childbearing age in the latest version.

Class	Share in %
NK	10.0

Water hazard class: Void.

Other regulations, limitations and prohibitive regulations Void.

Substances of very high concern (SVHC) according to REACH, Article 57 Not applicable.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.**SECTION 16: Other information**

All information and recommendations are believed to be correct as of the date of this Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. medac shall not be held liable for any damage resulting from handling or from contact with the above product.

Relevant phrases

H226 Flammable liquid and vapour.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H360D May damage the unborn child.

Department issuing data specification sheet: Product Safety

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Contact: productsafety@medac.de**Replaces version from:** 05.06.2013**Reason for alteration:**

Change of manufacturer's address and of article number(s).

Change of contact address.

General editorial revision.

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

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