

Safety Data Sheet Mohs HRP-Green kit (EU)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Mohs HRP-Green kit (EU)

Product number K092

Brand Mohs HRP-Green kit

Other means of identification

COMPONENT 1 (K074C) COMPONENT 2 (K074B) COMPONENT 3 (K092)

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

In Vitro Diagnostic Use

1.3 Details of the supplier of the safety data sheet

Name Diagnostic Biosystems Address 6616 Owens Drive Pleasanton CA 94588

USA

Telephone (888) 896-3350

email customersupport@dbiosys.com

1.4 Emergency telephone number

(925) 484-3350 (9AM-6PM, Monday - Friday, Pacific Standard Time)

SECTION 2: Hazards identification

General hazard statement

For Professional Users Only

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

- Acute toxicity, inhalation (chapter 3.1), Cat. 5, H333
- Serious eye damage/eye irritation (chapter 3.3), Cat. 2, H319

- Skin corrosion/irritation (chapter 3.2), Cat. 2, H315
- Toxic to reproduction (chapter 3.7), Cat. 1B, H360

For the full text corresponding to the "H"-codes displayed in this section, refer to Section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms



1. Exclamation mark; 2. Health hazard

Signal word	Danger
0.9	= 49

Hazard	statements
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H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H332	Harmful if inhaled
H360	May damage fertility or the unborn child

Precautionary statements

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264	Wash hands thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eve protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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.
P312 Call a POISON CENTER/doctor if you feel unwell.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

P405 Store locked up.

P501 Dispose of contents/container to a licensed disposal company.

2.3 Other hazards

No other hazards identified.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Component 1.

1. 3,3',5,5'-TETRAMETHYLBENZIDINE

Concentration < 0.1 % (weight)

Other names / synonyms [1,1'-Biphenyl]-4,4'-diamine, 3,3',5,5'-tetramethyl-;

CAS no. 54827-17-7

2. Methyl pyrrolidone

Concentration < 15 % (volume)

Other names / synonyms 2-Pyrrolidinone, 1-methyl-; N-methyl-2-pyrrolidone; N-Methylpyrrolidone

EC no. 212-828-1 CAS no. 872-50-4 Index no. 606-021-00-7

- Reproductive toxicity (chapter 3.7), Cat. 1B

- Specific target organ toxicity, single exposure (chapter 3.8), Cat. 3

- Skin corrosion/irritation (chapter 3.2), Cat. 2 - Eye damage/irritation (chapter 3.3), Cat. 2

H315 Causes skin irritation

H319 Causes serious eye irritation H335 May cause respiratory irritation H360D May damage the unborn child SCLs/M-factors/ATEs STOT SE 3; H335: $C \ge 10 \%$

Component 2.

1. 2-METHOXYETHANOL

Concentration < 7 % (volume)

Other names / synonyms Ethanol, 2-methoxy-; Ethylene glycol monomethyl ether

EC no. 203-713-7 CAS no. 109-86-4 Index no. 603-011-00-4

- Flammable liquids (chapter 2.6), Cat. 3

- Reproductive toxicity (chapter 3.7), Cat. 1B - Acute toxicity, inhalation (chapter 3.1), Cat. 4

- Acute toxicity, dermal (chapter 3.1), Cat. 4

- Acute toxicity, oral (chapter 3.1), Cat. 4

H226 Flammable liquid and vapor

H302 Harmful if swallowed
H312 Harmful in contact with skin

TIG12 TIGHTHUL III CONTACT WILLI SK

H332 Harmful if inhaled

H360FD May damage fertility. May damage the unborn child.

2. Methyl pyrrolidone

Concentration < 15 % (volume)

Other names / synonyms 2-Pyrrolidinone, 1-methyl-; N-methyl-2-pyrrolidone; N-Methylpyrrolidone

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- Skin corrosion/irritation (chapter 3.2), Cat. 2 - Eye damage/irritation (chapter 3.3), Cat. 2

H315 Causes skin irritation

H319 Causes serious eye irritation H335 May cause respiratory irritation H360D May damage the unborn child SCLs/M-factors/ATEs STOT SE 3; H335: $C \ge 10 \%$

Component 3. 1. Tromethamine

Concentration < 1.5 % (weight)

Other names / synonyms 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-; Tris; Trometamol;

CAS no. 77-86-1

2. 2-[[]4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol

 Concentration
 < 0.1 % (volume),</td>

 EC no.
 618-344-0

 CAS no.
 9002-93-1

3. Reaction mass of: 5-Chloro-2-methyl4- isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)

Concentration < 0.1 % (volume), 3

Other names / synonyms 3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-

isothiazolone; Kathon 886;

EC no. –

CAS no. 55965-84-9 Index no. 613-167-00-5

- Acute toxicity, inhalation (chapter 3.1), Cat. 2
- Acute toxicity, dermal (chapter 3.1), Cat. 2
- Acute toxicity, oral (chapter 3.1), Cat. 3
- Skin corrosion/irritation (chapter 3.2), Cat. 1C
- Eye damage/irritation (chapter 3.3), Cat. 1
- Sensitization skin (chapter 3.4), Cat. 1A
- Hazardous to the aquatic environment, short-term (acute) (chapter 4.1), Cat. 1
- Hazardous to the aquatic environment, long-term (chronic) (chapter 4.1), Cat. 1

H301 Toxic if swallowed

H310 Fatal in contact with skin

H314 Causes severe skin burns and eye damage

H317 May cause an allergic skin reaction
H318 Causes serious eye damage

H330 Fatal if inhaled

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

SCLs/M-factors/ATEs Skin Corr. 1C; $: C \ge ,6 \%$

Skin Irrit. 2; H315: $.06\% \le C < .6\%$

Eye Dam. 1; : C ≥ ,6 %

Eye Irrit. 2; H319: $,06 \% \le C < ,6 \%$ Skin Sens. 1A; $:C \ge ,0015 \%$

M=100 M=100

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes Consult a physician. Show this safety data sheet to the doctor in attendance.

Following inhalation If breathed in, move person into fresh air. If not breathing, give artificial

respiration.

Do NOT induce vomiting. Never give anything by mouth to an unconscious

person. Rinse mouth with water. Consult a physician.

Following skin contact Rinse with plenty of water. Get medical attention if irritation develops and

persists.

Following eye contact Rinse thoroughly with plenty of water for at least 15 minutes. Get medical

attention if symptoms occur.

Following ingestion Call a poison center or doctor if you feel unwell. If vomiting occurs naturally,

have victim lean forward to reduce the risk of aspiration. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything

by mouth to an unconscious person.

Acute and delayed symptoms and effects: May cause gastrointestinal irritation. Signs/symptoms may include abdominal pain, stomach upset,

nausea, vomiting and diarrhea.

Self-protection of the first aider Ensure adequate ventilation. Use personal protective equipment. For

personal protection see section 8.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Use extinguishing media appropriate for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Reaction mass of: 5-Chloro-2-methyl4- isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): Carbon oxide. Nitrogen oxides.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

Further information

No data available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

Ensure adequate ventilation. Use personal protective equipment. For personal protection see section 8.

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

6.2 Environmental precautions

Should not be released into the environment. See Section 12 for additional ecological information.

6.3 Methods and material for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

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

8.1 Control parameters

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2-METHOXYETHANOL

Cal/OSHA: 5 ppm PEL inhalation; NIOSH: 0.1 ppm REL inhalation; OSHA: 25 ppm PEL inhalation; 80 mg/m3 PEL inhalation

8.2 Exposure controls

Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Individual protection measures, such as personal protective equipment

Pictograms







Eye and face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin 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.

Body protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards

No data available

Control banding approach

No data available.

Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state Liquid
Appearance Clear
Colour Colorless
Odour Odorless

Odour threshold No data available.

Ha No data available Melting point/freezing point No data available. Boiling point or initial boiling point and boiling range No data available. Flash point No data available. Evaporation rate No data available. Flammability No data available. Lower and upper explosion limit/flammability limit No data available. Vapor pressure No data available. Relative vapor density No data available. Density and/or relative density No data available. Solubility No data available. Partition coefficient n-octanol/water (log value) No data available. No data available. Auto-ignition temperature Decomposition temperature No data available. Kinematic viscosity No data available. Explosive properties No data available. Oxidizing properties No data available.

Particle characteristics

No data available.

9.2 Other information

9.2.1 Information with regard to physical hazard classes

No data available.

9.2.2 Other safety characteristics

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

None under normal use conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

None under normal use conditions.

10.4 Conditions to avoid

Exposure to moisture.

Avoid storing in direct sunlight and avoid extremes of temperature.

Heat, flames and sparks.

10.6 Hazardous decomposition products

Other decomposition products - No data available In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

The ATE (gas inhalation) of the mixture is: 64285.71 ppmV

Skin corrosion/irritation

Based on available data, classification data are not met

Serious eye damage/irritation

Risk of serious damage to eyes.

Respiratory or skin sensitization

Based on available data, classification data are not met

Germ cell mutagenicity

Based on available data, classification data are not met

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Based on available data, classification data are not met

STOT-single exposure

No data available.

STOT-repeated exposure

No data available.

Aspiration hazard

No data available.

11.2 Information on other hazards

Endocrine disrupting properties

No data available.

Other information

No data available.

SECTION 12: Ecological information

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

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No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product disposal

Offer surplus and non-recyclable solutions to a licensed disposal company.

Packaging disposal

Dispose of as unused product.

Waste treatment

No data available

Sewage disposal

Do not let product enter drains

Other disposal recommendations

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

SECTION 14: Transport information

14.1	UN Number	None
14.2	UN Proper Shipping Name	None
14.3	Transport hazard class(es)	None
14.4	Packing group	None
14.5	Environmental hazards	None
14.6	Special precautions for user	None
14.7	Maritime transport in bulk according to IMO instruments	None

SECTION 15: Regulatory information

15.2 Chemical Safety Assessment

The supplier of this product has not conducted any Chemical Safety Assessment

SECTION 16: Other information

Full text of hazard statements referenced in Section 2

H315 Causes skin irritation

H319 Causes serious eye irritation
H333 May be harmful if inhaled

H360 May damage fertility or the unborn child [effect, route]

SDS-0108, Rev.B

Further information/disclaimer

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