

acc. to Regulation (EC) No. 1907/2006 (REACH)

Capsule Stains - Kit

Version number: GHS 1.0 Date of compilation: 2023-03-15

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

1.1 **Product identifier**

Capsule Stains - Kit Trade name

Alternative number(s) K004L

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

Relevant identified uses Laboratory Chemicals, Analytical Purpose, Bio-

chemical Ánalysis

For InVitro Diagnostic Use

1.3 Details of the supplier of the safety data sheet

HiMedia Laboratories Pvt. Ltd. Plot No. C40, Road No. 21Y, Wagle Industrial Area, MIDC Thane West Maharashtra 400604 India

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e-mail (competent person) info@himedialabs.com (HiMedia Laboratories Pvt.

Ltd)

1.4 **Emergency telephone number**

This number is only available during the follow-**Emergency information service**

ing office hours: Mon-Fri 09:00 AM - 05:00 PM

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification acc. to GHS

Section	Hazard class	Category	Hazard class and cat- egory	Hazard state- ment	
3.45	skin sensitisation	1	Skin Sens. 1	H317	
3.6	carcinogenicity	1B	Carc. 1B	H350	

For full text of abbreviations: see SECTION 16.

2.2 **Label elements**

Labelling

- Signal word danger

- Pictograms

GHS07, GHS08



- Hazard statements

H317 May cause an allergic skin reaction.

H350 May cause cancer.

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- Precautionary statements

P201 Obtain special instructions before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protec-

tion.

P308+P313 IF exposed or concerned: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container to industrial combustion plant.

- Hazardous ingredients for labelling Formaldehyde

2.3 Other hazards

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of \geq 0,1%.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS
Methylene Blue (Aqueous)		≥ 90	
Formaldehyde	CAS No 50-00-0 EC No 200-001-8 Index No 605-001-00-5	<1	Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 Skin Corr. 1B / H314 Eye Dam. 1 / H318 Skin Sens. 1 / H317 Muta. 2 / H341 Carc. 1B / H350 STOT SE 3 / H335

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
Formaldehyde	Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Dam. 1; H318: C ≥ 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % Skin Sens. 1; H317: C ≥ 0.2 % STOT SE 3; H335: C ≥ 5 %	-	100 ^{mg} / _{kg} 300 ^{mg} / _k g 3 ^{mg} / _I /4h	oral dermal inhalation: vapour

For full text of abbreviations: see SECTION 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO2)

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Nature of decomposition products not known.

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

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6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

- Specific designs for storage rooms or vessels
- Storage temperature

Recommended storage temperature: 10 – 30 °C

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)

Coun- try	Name of agent	CAS No	Identi- fier		TWA [mg/m³]	STEL [ppm]		Ceiling-C [mg/m³]		Source
EU	formaldehyde	50-00-0	IOELV	0.3	0.37	0.74	0.6		sect	2019/ 983/EU
GB	formaldehyde	50-00-0	WEL	2	2.5	2	2.5			EH40/ 2005

Notation Ceiling-C

sect

ceiling value is a limit value above which exposure should not occur

limit value of 0,62 mg/m3 or 0,5 ppm for the health care, funeral and embalming sectors until 11 July 2024

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Notation

short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute peri-STEL

od (unless otherwise specified)

TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours

time-weighted average (unless otherwise specified)

8.2 **Exposure controls**

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leaktightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	Refer SDS of Nigrosin Stain 10%w/v (S025) and Methylene Blue (S021) for respective appearance
Odour	Not applicable
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined

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Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure not determined

Density and/or relative density

Density	not determined
Relative vapour density	information on this property is not available

Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification acc. to GHS

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Formaldehyde	50-00-0	oral	100 ^{mg} / _{kg}
Formaldehyde	50-00-0	dermal	300 ^{mg} / _{kg}
Formaldehyde	50-00-0	inhalation: vapour	3 ^{mg} / _l /4h

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

May cause cancer.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

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SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0.1\%$.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0.1\%$.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

14.1 UN number or ID number

IMDG-Code UN 3316 ICAO-TI UN 3316

14.2 UN proper shipping name

IMDG-Code CHEMICAL KIT ICAO-TI Chemical kit

14.3 Transport hazard class(es)

IMDG-Code 9
ICAO-TI 9

14.4 Packing group

IMDG-Code II

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ICAO-TI II

14.5 Environmental hazards not assigned

14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

International Maritime Dangerous Goods Code (IMDG) - Additional information

Marine pollutant Danger label(s) 9



Special provisions (SP) 251, 340

Excepted quantities (EQ) -> SP340

Limited quantities (LQ) -> SP251

EmS F-A, S-P

Stowage category A

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Danger label(s) 9



Special provisions (SP) A44, A163

Excepted quantities (EQ) E0
Limited quantities (LQ) 1 kg

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

Deco-Paint Directive

VOC content	0.5 %
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Industrial Emissions Directive (IED)

VOC content	0.5 %

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

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Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

Water Framework Directive (WFD)

List of pollutants (WFD)

Name of substance	CAS No	Listed in	Remarks
Formaldehyde		a)	

Legend

A) Indicative list of the main pollutants

Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

National inventories

Country	Inventory	Status
EU	REACH Reg.	all ingredients are listed
US	TSCA	all ingredients are listed as "ACTIVE"

Legend

REACH Reg. REACH registered substances
TSCA Toxic Substance Control Act

15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2019/983/EU	Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
Acute Tox.	Acute toxicity
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
Carc.	Carcinogenicity
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-li- cence/)
EINECS	European Inventory of Existing Commercial Chemical Substances

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Abbr.	Descriptions of used abbreviations
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
Muta.	Germ cell mutagenicity
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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Classification procedure

Physical and chemical properties: The classification is based on tested mixture. Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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