according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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# Sudan I (C.I. 12055) extra pure

article number: **1H5Y** Version: **2.0 en** Replaces version of: 2022-07-27 Version: (1)

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

1.1 Product identifier

Identification of the substance

Article number

Registration number (REACH)

Sudan I (C.I. 12055) extra pure

1H5Y

611-056-00-6

212-668-2

842-07-9

It is not required to list the identified uses because the substance is not subject to registration according to REACH (< 1 t/a).

Index number in CLP Annex VI

EC number

CAS number

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

Relevant identified uses:

Uses advised against:

Laboratory and analytical use Laboratory chemical

Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household). Food, drink and animal feedingstuffs.

### **1.3** Details of the supplier of the safety data sheet

Carl Roth GmbH + Co. KG Schoemperlenstr. 3-5 D-76185 Karlsruhe Germany

**Telephone:**+49 (0) 721 - 56 06 0 **Telefax:** +49 (0) 721 - 56 06 149 **e-mail:** sicherheit@carlroth.de **Website:** www.carlroth.de

Competent person responsible for the safety data Department Health, Safety and Environment sheet:

# e-mail (competent person):

# sicherheit@carlroth.de

# **1.4** Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	+353 1 809 2166	https:// www.poisons.ie/

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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# **SECTION 2: Hazards identification**

# 2.1 Classification of the substance or mixture

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

Section	Hazard class		Hazard class and category	Hazard statement
3.4S	Skin sensitisation	1	Skin Sens. 1	H317
3.5	Germ cell mutagenicity		Muta. 2	H341
3.6	Carcinogenicity	2	Carc. 2	H351
4.1C	Hazardous to the aquatic environment - chronic hazard	4	Aquatic Chronic 4	H413

For full text of abbreviations: see SECTION 16

# The most important adverse physicochemical, human health and environmental effects

Spillage and fire water can cause pollution of watercourses.

# 2.2 Label elements

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

#### Signal word Warning

#### Pictograms

GHS07, GHS08



### **Hazard statements**

H317	May cause an allergic skin reaction
H341	Suspected of causing genetic defects
H351	Suspected of causing cancer
H413	May cause long lasting harmful effects to aquatic life

# **Precautionary statements**

#### **Precautionary statements - prevention**

P273Avoid release to the environmentP280Wear protective gloves/eye protection

### **Precautionary statements - response**

P302+P352IF ON SKIN: Wash with plenty of waterP308+P313IF exposed or concerned: Get medical advice/attention

For professional users only

#### Labelling of packages where the contents do not exceed 125 ml Signal word: Warning



according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

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H317	May cause an allergic skin reaction.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H413	May cause long lasting harmful effects to aquatic life.
P280	Wear protective gloves/eye protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P308+P313	IF exposed or concerned: Get medical advice/attention.

#### 2.3 Other hazards

#### **Results of PBT and vPvB assessment**

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Name of substance	Sudan I (C.I. 12055)
Molecular formula	$C_{16}H_{12}N_2O$
Molar mass	248,3 <sup>g</sup> / <sub>mol</sub>
CAS No	842-07-9
EC No	212-668-2
Index No	611-056-00-6

# **SECTION 4: First aid measures**

### 4.1 Description of first aid measures



#### **General notes**

Take off contaminated clothing.

#### **Following inhalation**

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following skin contact

Rinse skin with water/shower. After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician.

#### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

### **Following ingestion**

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

# 4.2 Most important symptoms and effects, both acute and delayed

Allergic reactions



according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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# **4.3 Indication of any immediate medical attention and special treatment needed** none

# **SECTION 5: Firefighting measures**

# 5.1 Extinguishing media



### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water, foam, dry extinguishing powder, ABC-powder

# Unsuitable extinguishing media

water jet

# 5.2 Special hazards arising from the substance or mixture

Combustible.

#### Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

# **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe dust.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

### 6.3 Methods and material for containment and cleaning up

#### Advice on how to contain a spill

Covering of drains. Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically. Control of dust.

# Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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### 6.4 Reference to other sections

Hazardous combustion products: see section 5. 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

Avoid exposure. Avoid dust formation.

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

Removal of dust deposits.

#### Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

### 7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place.

### Incompatible substances or mixtures

Observe hints for combined storage.

### Consideration of other advice:

#### **Ventilation requirements**

Use local and general ventilation.

### Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

### 7.3 Specific end use(s)

No information available.

# **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

### National limit values

### **Occupational exposure limit values (Workplace Exposure Limits)**

Coun try	Name of agent	CAS No	Identifi- er	TWA [mg/ m³]	STEL [mg/ m³]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
IE	dusts, non-specific		OELV	10			i	S.I. No. 619 of 2001
IE	dusts, non-specific		OELV	4			r	S.I. No. 619 of 2001

Notation

 

 Ceiling-C
 Ceiling value is a limit value above which exposure should not occur

 i
 Inhalable fraction

 r
 Respirable fraction

 STEL
 Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15minute period (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)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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Human health values								
Relevant DN	ELs and other t	hreshold levels						
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time				
DNEL	11,2 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects				
DNEL	3,2 mg/kg bw/ day	human, dermal	worker (industry)	chronic - systemic effects				

# **Environmental values**

Relevant				
End- point	Threshold level	Organism	Environmental com- partment	Exposure time
PNEC	41,8 <sup>µg</sup> / <sub>l</sub>	aquatic organisms freshwater		short-term (single instance)
PNEC	4,18 <sup>µg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single instance)
PNEC	100 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
PNEC	222,7 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single instance)
PNEC	22,3 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single instance)
PNEC	44,5 <sup>mg</sup> / <sub>kg</sub>	terrestrial organisms	soil	short-term (single instance)

### 8.2 Exposure controls

### Individual protection measures (personal protective equipment)

### Eye/face protection



Use safety goggle with side protection.

#### **Skin protection**



### hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. 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. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a consider-able reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

### • type of material

NBR (Nitrile rubber)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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#### material thickness

- >0,11 mm
- breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### • other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

#### **Respiratory protection**



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

#### **Environmental exposure controls**

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	solid
Colour	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not applicable
Kinematic viscosity	not relevant
Solubility(ies)	
Water solubility	(practically insoluble)
Partition coefficient	
Partition coefficient n-octanol/water (log value):	5,51 (ECHA)
Vapour pressure	not determined

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Density and/or relative density	
Density	not determined
Relative vapour density	Information on this property is not available.
Particle characteristics	No data available.
Other safety parameters	
Oxidising properties	none
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

9.2

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

# **10.3** Possibility of hazardous reactions

Violent reaction with: strong oxidiser

#### 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

Hazardous combustion products: see section 5.

# **SECTION 11: Toxicological information**

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

Classification according to GHS (1272/2008/EC, CLP)

### Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity					
Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	>10.000 <sup>mg</sup> / <sub>kg</sub>	rat		ECHA



according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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# 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

Suspected of causing genetic defects.

# Carcinogenicity

Suspected of causing 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.

# Symptoms related to the physical, chemical and toxicological characteristics

### • If swallowed

Data are not available.

# • If in eyes

Data are not available.

### • If inhaled

Data are not available.

### • If on skin

May produce an allergic reaction, pruritis, localised redness

### • Other information

Substance not yet fully tested

# **11.2 Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

# **11.3** Information on other hazards

There is no additional information.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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# **SECTION 12: Ecological information**

# 12.1 Toxicity

May cause long lasting harmful effects to aquatic life.

# Aquatic toxicity (acute)

Endpoint Value		Species	Source	Exposure time			
EC50	>100 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	ECHA	48 h			
ErC50	41,8 <sup>mg</sup> / <sub>l</sub>	algae	ECHA	72 h			

# Aquatic toxicity (chronic)

Endpoint	Value	Species	Source	Exposure time
EC50	>1.000 <sup>mg</sup> / <sub>l</sub>	microorganisms	ECHA	180 min

# 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 2,191 <sup>mg</sup>/<sub>mg</sub> Theoretical Oxygen Demand (with nitrification): 2,465 <sup>mg</sup>/<sub>mg</sub> Theoretical Carbon Dioxide: 2,836 <sup>mg</sup>/<sub>mg</sub>

# Biodegradation

Not readily biodegradable.

Process of degradability				
Process	Degradation rate	Time		
carbon dioxide generation	<10 %	28 d		

# 12.3 Bioaccumulative potential

The substance fulfils the very bioaccumulative criterion.

n-octanol/water (log KOW)	5,51 (ECHA)
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### 12.4 Mobility in soil

Data are not available.

# 12.5 Results of PBT and vPvB assessment

Data are not available.

# 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

### 12.7 Other adverse effects

Data are not available.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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# **SECTION 13: Disposal considerations**

### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### 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

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

#### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

#### Properties of waste which render it hazardous

- **HP7** carcinogenic
- HP 11 mutagenic
- HP 13 sensitising
- HP 14 ecotoxic

#### 13.3 Remarks

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

# **SECTION 14: Transport information**

14.1	UN number or ID number	not subject to transport regulations
14.2	UN proper shipping name	not assigned
14.3	Transport hazard class(es)	none
14.4	Packing group	not assigned
14.5	Environmental hazards	non-environmentally hazardous acc. to the dan- gerous goods regulations

# 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.

14.8 Information for each of the UN Model Regulations

# **International Maritime Dangerous Goods Code (IMDG) - Additional information** Not subject to IMDG.

**International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information** Not subject to ICAO-IATA.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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# **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)

**Restrictions according to REACH, Annex XVII** 

Dangerous substances with restrictions (REACH, Annex XVII)					
Name of substance	Name acc. to inventory	CAS No	Restriction	No	
Sudan I (C.I. 12055)	substances in tattoo inks and perman- ent make-up		R75	75	

#### Legend

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such sub-stances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or R75 are present in the following circumstances (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive cat-egory 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than: substance is present in the mixture in a concentration equal to or greater than: (i) 0,1 % by weight, if the substance is used solely as a pH regulator; (ii) 0,01 % by weight, in all other cases; (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; mixture in a concentration equal to or greater than 0,00005 % by weight: (i) "Rinse-off products"; (i) "Not to be used in products applied on mucous membranes";
(ii) "Not to be used in eye products";
(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration in the condition in the condition specified in that column; (n) In the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the strictest is paragraph 1 apply to that substance. 4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6). 5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of apthat it then falls within a different one of those points from the one within which it fell previously, and the date of ap-plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, para-graph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification. 6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information: (a) the statement "Mixture for use in tattoos or permanent make-up"; (a) the statement "Mixture for use in tattoos or permanent make-up"; (b) a reference number to uniquely identify the batch; (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Im-writing the herearded as ingredients is formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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#### Legend

this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredi-

(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1; (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentra-tion limit specified in Appendix 13; (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below

the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible. The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the

market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this para-

graph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or gener-ate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Device the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

# List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Not listed.

#### **Seveso Directive**

2012/	2012/18/EU (Seveso III)					
Νο	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the ap- plication of lower and upper-tier re- quirements	Notes			
	not assigned					

#### **Deco-Paint Directive**

VOC content	0 %
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#### Industrial Emissions Directive (IED)

VOC content	0 %
-------------	-----

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

not listed

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

not listed

#### Water Framework Directive (WFD)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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ist of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Sudan I (C.I. 12055)	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		a)	

Legend a)

Indicative list of the main pollutants

### Regulation on the marketing and use of explosives precursors

not listed

### **Regulation on drug precursors**

not listed

### Regulation on substances that deplete the ozone layer (ODS)

not listed

# Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

# **Regulation on persistent organic pollutants (POP)**

not listed

### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

### **National inventories**

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TR	CICR	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Sudan I (C.I. 12055) extra pure

#### article number: 1H5Y

Country	Inventory	Status
VN	NCI	substance is listed
CICR CSCL-ENCS DSL ECSI IECSC INSQ KECI NCI NZIOC PICCS	Domestic Substances List EC Substance Inventory (I Inventory of Existing Chei National Inventory of Che Korea Existing Chemicals National Chemical Invent New Zealand Inventory of	Control Regulation Chemical Substances (CSCL-ENCS) (DSL) EINECS, ELINCS, NLP) mical Substances Produced or Imported in China emical Substances Inventory ory of Chemicals nemicals and Chemical Substances (PICCS) nces cce Inventory

# 15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance.

# **SECTION 16: Other information**

# Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.2		Hazard statements: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
14.7	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional in- formation: not assigned		yes
15.1	Restrictions according to REACH, Annex XVII: not listed	Restrictions according to REACH, Annex XVII	yes
15.1		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	yes
15.1	VOC content: 0 % 0 <sup>g</sup> / <sub>l</sub>	VOC content: 0 %	yes
15.1	VOC content: 0 <sup>g</sup> / <sub>l</sub>		yes
15.1		Regulation on persistent organic pollutants (POP): not listed	yes
15.1		Other information: Directive 94/33/EC on the protection of young people at work. Observe employment restric- tions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.	yes

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Sudan I (C.I. 12055) extra pure

# article number: 1H5Y

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.1		National inventories: change in the listing (table)	yes

# Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identi- fier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	= EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Na- tions
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	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
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
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)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
STEL	Short-term exposure limit

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Sudan I (C.I. 12055) extra pure

### article number: 1H5Y

Abbr.	Descriptions of used abbreviations
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

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).

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

Code	Text	
H317	May cause an allergic skin reaction.	
H341	Suspected of causing genetic defects.	
H351	Suspected of causing cancer.	
H413	May cause long lasting harmful effects to aquatic life.	

#### Disclaimer

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