### Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Date of issue: 04/12/2019 Revision date: 05/01/2023 Supersedes version of: 18/12/2019 Version: 1.2

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

#### **1.1. Product identifier**

Product form	: Mixture
Name	: Harris's Hematoxylin for Papanicolaou
Trade name	: Harris's Hematoxylin for Papanicolaou
UFI	: 9D40-Q0GX-J004-J3V6
Product code	: HEMA-HPS

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

#### No additional information available

#### No additional information available

#### 1.4. Emergency telephone number

Country/Area	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Belfast Centre) Royal Victoria Hospital	Grosvenor Road BT12 6BA	0344 892 0111	

#### **SECTION 2: Hazards identification**

# 2.1. Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP] Acute toxicity (dermal), Category 4 H312 Acute toxicity (inhal.), Category 4 H332 Full text of H and EUH statements: see section 16 H312 Adverse physicochemical, human health and environmental effects No additional information available

#### 2.2. Label elements

Labelling according to Regulation (EC)	No. 1272/2008 [CLP]
Hazard pictograms (CLP)	GHS07
Signal word (CLP)	: Warning
Contains	: ALCOHOL
Hazard statements (CLP)	: H312+H332 - Harmful in contact with skin or if inhaled.
Precautionary statements (CLP)	<ul> <li>P264 - Wash hands, forearms and face thoroughly after handling.</li> <li>P280 - Wear protective gloves/protective clothing/eye protection/face protection.</li> <li>P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.</li> <li>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove context language if accent and accent and a Continue riseing.</li> </ul>
2.3. Other hazards	contact lenses, if present and easy to do. Continue rinsing.

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

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The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

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

#### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
aluminium sulphate	CAS-No.: 10043-01-3 EC-No.: 233-135-0	5	Eye Dam. 1, H318
ALCOHOL	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002-00-5	4	Flam. Liq. 2, H225
	CAS-No.: 517-28-2 EC-No.: 205-386-6 EC Index-No.: 01- 2120804644-	0,6	Not classified
WATER	CAS-No.: 7732-18-5 EC-No.: 231-791-2	Balance	Not classified

Full text of H and EUH statements: see section 16

SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures general	: Get medical advice/attention if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Give oxygen or artificial respiration if necessary.
First-aid measures after skin contact	: Wash skin with plenty of water. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water. If swallowed, seek medical advice immediately and show this container or label.
4.2. Most important symptoms and e	fects, both acute and delayed
Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause moderate irritation.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: May cause irritation to the digestive tract.
4.3 Indication of any immediate med	ical attention and special treatment needed

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable extinguishing media Unsuitable extinguishing media	<ul><li>Carbon dioxide. Water spray. Dry powder.</li><li>Strong water jet.</li></ul>	
5.2. Special hazards arising from the substance or mixture		
No additional information available		

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5.3. Advice for firefighters	
Firefighting instructions Protection during firefighting	<ul> <li>Exercise caution when fighting any chemical fire.</li> <li>Do not enter fire area without proper protective equipment, including respiratory protection.</li> </ul>
SECTION 6: Accidental release meas	sures
6.1. Personal precautions, protective equ	uipment and emergency procedures
For emergency responders	
Protective equipment	: Equip cleanup crew with proper protection. Do not attempt to take action without suitable protective equipment.
6.2. Environmental precautions	
No additional information available	
6.3. Methods and material for containme	nt and cleaning up
For containment	: Absorb spilled material with sand or earth. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
6.4. Reference to other sections	
See Heading 8. For further information refer to se	ction 13.
SECTION 7: Handling and storage	
7.1. Precautions for safe handling	
Hygiene measures	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
7.2. Conditions for safe storage, including	ig any incompatibilities
Storage conditions	: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in a well-ventilated place. Keep container tightly closed.
Special rules on packaging	: Keep only in original container. Store in a closed container.
7.3. Specific end use(s)	
Laboratory chemicals.	
SECTION 8: Exposure controls/perso	onal protection

#### 8.1. Control parameters

National occupational exposure and biological limit values

Harris's Hematoxylin for Papanicolaou		
EU - Indicative Occupational Exposure Limit (IOEL)		
IOEL TWA	1090 mg/m³	
	1000 ppm	
ALCOHOL (64-17-5)		
France - Occupational Exposure Limits		
Local name	Alcool éthylique	
VME (OEL TWA)	1900 mg/m³	
	1000 ppm	

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ALCOHOL (64-17-5)		
VLE (OEL Ceiling/STEL)	9500 mg/m³	
	5000 ppm	
Remark	Valeurs recommandées/admises	
Germany - Occupational Exposure Limits (TRGS 900)		
Local name	Ethanol	
AGW (OEL TWA)	960 mg/m³	
	500 ppm	
Remark	DFG,Y	
Portugal - Occupational Exposure Limits		
Local name	Etanol (Álcool etílico)	
OEL STEL	1000 ppm	
Spain - Occupational Exposure Limits		
Local name	Etanol (Alcohol etílico)	
VLA-EC (OEL STEL)	1910 mg/m <sup>3</sup>	
	1000 ppm	
Remark	s (Esta sustancia tiene prohibida total o parcialmente su comercialización y uso como fitosanitario y/o como biocida. Para una información detallada acerca de las prohibiciones consúltese: Base de datos de productos biocidas: http://www.msssi.gob.es/ciudadanos/productos.do?tipo=plaguicidas Base de datos de productos fitosanitarios http://www.magrama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/Lista_sa.pdf).	
United Kingdom - Occupational Exposure Limits		
Local name	Ethanol	
WEL TWA (OEL TWA)	1920 mg/m <sup>3</sup>	
	1000 ppm	

#### **DNEL and PNEC**

Harris's Hematoxylin for Papanicolaou		
DNEL/DMEL (Workers)		
Acute - systemic effects, dermal	343 mg/kg bodyweight/day	
Acute - systemic effects, inhalation	950 mg/m³	
DNEL/DMEL (General population)		
Acute - systemic effects, dermal	206 mg/kg bodyweight	
Acute - systemic effects, inhalation	114 mg/m <sup>3</sup>	
PNEC (Water)		
PNEC aqua (freshwater)	0,96 mg/l	
PNEC aqua (marine water)	0,79 mg/l	
PNEC (Sediment)		
PNEC sediment (freshwater)	3,6 mg/kg dwt	
PNEC (Soil)		
PNEC soil	0,63 mg/kg dwt	

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#### 8.2. Exposure controls

#### **Personal protection equipment**

#### Personal protective equipment:

Avoid all unnecessary exposure. EN 374.



#### Eye and face protection

Eye protection: Safety glasses

Eye protection				
Type         Field of application         Characteristics         Standard				
			EN 166	

#### **Skin protection**

#### Skin and body protection:

Wear suitable protective clothing

Skin and body protection	
Туре	Standard
	EN 340

#### Hand protection:

protective gloves

Hand protection					
Туре	Material	Permeation	Thickness (mm)	Penetration	Standard
	Nitrile rubber (NBR)	6 (> 480 minutes)	0.50 mm		EN ISO 374

#### Other skin protection

Materials for protective clothing: Wear safety footwear

Other skin protection Materials for protective clothing		
Condition	Material	Standard
		EN ISO 20345

#### Respiratory protection

#### **Respiratory protection:**

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
filtering face piece			EN 136, EN 140, EN 14387

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#### **Environmental exposure controls**

#### Other information:

Wash hands with water as a precaution. Do not eat, drink or smoke during use.

9.1. Information on basic physical and cl	iemical properties
Physical state	: Liquid
Colour	: Purple.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
рН	: 2,3 – 2,7
Viscosity, kinematic	: Not available
Solubility	: Miscible with water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50 °C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20 °C	: Not available
Particle characteristics	: Not applicable
9.2. Other information	
Other safety characteristics	
VOC content	: 4%

#### 10.1. Reactivity

No additional information available

**10.2. Chemical stability** 

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

Oxidizing materials. May react with aluminium.

**10.4. Conditions to avoid** 

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5. Incompatible materials

Aluminium.

**10.6. Hazardous decomposition products** 

No additional information available

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SECTION 11: Toxicological information	
11.1. Information on hazard classes as define	d in Regulation (EC) No 1272/2008
······································	Not classified Harmful in contact with skin. Harmful if inhaled.
Harris's Hematoxylin for Papanicolaou	
LD50 oral rat	7,06 mg/kg
LD50 oral	1930 mg/kg
LC50 inhalation rat (mg/l)	20 mg/l
ATE CLP (dermal)	1100 mg/kg bodyweight
ATE CLP (vapours)	11 mg/l/4h
ATE CLP (dust,mist)	1,5 mg/l/4h
aluminium sulphate (10043-01-3)	
LD50 oral rat	<ul> <li>&gt; 2000 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline</li> <li>420 (Acute Oral Toxicity - Fixed Dose Method)</li> </ul>
LD50 dermal rabbit	> 1167,5 mg/kg bodyweight Animal: rabbit, Animal sex: female, Guideline: OECD Guideline 402 (Acute Dermal Toxicity)
Skin corrosion/irritation :	Not classified pH: 2,3 – 2,7
Serious eye damage/irritation :	Not classified pH: 2,3 – 2,7
Respiratory or skin sensitisation :	Not classified
Germ cell mutagenicity :	Not classified
Carcinogenicity : Reproductive toxicity :	Not classified Not classified
aluminium sulphate (10043-01-3)	
LOAEL (animal/male, F0/P)	27,371 mg/kg bodyweight Animal: other:rat and mouse, Animal sex: male, Guideline: EPA OTS 798.4700 (Reproduction and Fertility Effects), Remarks on results: other:Generation: Effects on spermatogenesis, testis, epididymis, in the ductus deferens, interstitium (migrated information)
NOAEL (animal/female, F0/P)	310 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EU Method B.35 (Two-Generation Reproduction Toxicity Test), Remarks on results: other:Generation: F3 (migrated information)
NOAEL (animal/female, F1)	310 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EU Method B.35 (Two-Generation Reproduction Toxicity Test)
STOT-single exposure :	Not classified
STOT-repeated exposure :	Not classified
Aspiration hazard :	Not classified
11.2. Information on other hazards	

No additional information available

SECTION 12: Ecological information			
12.1. Toxicity			
Hazardous to the aquatic environment, short-term (acute)	: Not classified		
Hazardous to the aquatic environment, long-term (chronic)	: Not classified		

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aluminium sulphate (10043-01-3)		
LC50 - Fish [1]	214,6 mg/l Test organisms (species): Pimephales promelas	
LC50 - Fish [2]	228,5 mg/l Test organisms (species): Pimephales promelas	
EC50 - Daphnia [1]	> 100 mg/l Test organisms (species): Daphnia magna	
EC50 72h - Algae [1]	> 100 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)	
LOEC (chronic)	27 mg/l Test organisms (species): Daphnia magna Duration: '28 d'	
NOEC (chronic)	12 mg/l Test organisms (species): Daphnia magna Duration: '28 d'	
12.2. Persistence and degradability		
Harris's Hematoxylin for Papanicolaou		
Persistence and degradability	Rapidly degradable	
ALCOHOL (64-17-5)		
Persistence and degradability	Rapidly degradable	
aluminium sulphate (10043-01-3)		
Persistence and degradability	Rapidly degradable	
(517-28-2)		
Persistence and degradability	Rapidly degradable	
WATER (7732-18-5)		
Persistence and degradability	Rapidly degradable	
12.3. Bioaccumulative potential		
No additional information available		
12.4. Mobility in soil		
No additional information available		
12.5. Results of PBT and vPvB assessment		
No additional information available		
12.6. Endocrine disrupting properties		
No additional information available		
12.7. Other adverse effects		
No additional information available		

SECTION 13: Disposal considerations		
13.1. Waste treatment methods		
Regional legislation (waste) Waste treatment methods	<ul><li>Disposal must be done according to official regulations.</li><li>Must follow special treatment according to local regulation.</li></ul>	

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

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14.1. UN number or ID number		
Not regulated for transport		
14.2. UN proper shipping name		
Proper Shipping Name (ADR) Proper Shipping Name (IMDG) Proper Shipping Name (IATA) Proper Shipping Name (ADN) Proper Shipping Name (RID)	<ul> <li>Not regulated</li> <li>Not regulated</li> <li>Not regulated</li> <li>Not regulated</li> <li>Not regulated</li> </ul>	
14.3. Transport hazard class(es)		
ADR Transport hazard class(es) (ADR)	: Not regulated	
IMDG Transport hazard class(es) (IMDG)	: Not regulated	
IATA Transport hazard class(es) (IATA)	: Not regulated	
ADN Transport hazard class(es) (ADN)	: Not regulated	
RID Transport hazard class(es) (RID)	: Not regulated	
14.4. Packing group		
Packing group (ADR) Packing group (IMDG) Packing group (IATA) Packing group (ADN) Packing group (RID)	<ul> <li>Not regulated</li> <li>Not regulated</li> <li>Not regulated</li> <li>Not regulated</li> <li>Not regulated</li> <li>Not regulated</li> </ul>	
14.5. Environmental hazards		
Other information	: No supplementary information available	
14.6. Special precautions for user		
Overland transport Not regulated		
Transport by sea Not regulated		
Air transport Not regulated		
Inland waterway transport Not regulated		
Rail transport Not regulated		
14.7. Maritime transport in bulk according to IMO instruments		
Not applicable		

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#### **SECTION 15: Regulatory information**

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### **EU-Regulations**

#### **REACH Annex XVII (Restriction List)**

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(a)	Harris's Hematoxylin for Papanicolaou ; ALCOHOL
40.	Harris's Hematoxylin for Papanicolaou ; ALCOHOL

#### **REACH Annex XIV (Authorisation List)**

Contains no REACH Annex XIV substances

#### REACH Candidate List (SVHC)

Contains no substance on the REACH candidate list

#### **PIC Regulation (Prior Informed Consent)**

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

#### **POP Regulation (Persistent Organic Pollutants)**

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

#### Ozone Regulation (2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

: 4 %

#### Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

#### VOC Directive (2004/42)

VOC content

#### **Explosives Precursors Regulation (2019/1148)**

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

#### **Drug Precursors Regulation (273/2004)**

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

#### **National regulations**

#### France

Occupational diseases	Occupational diseases	
Code	Description	
RG 20	Occupational diseases caused by arsenic and its mineral compounds	
RG 20 BIS	Primary bronchial cancer caused by inhalation of arsenical dust or vapors	
RG 84	Conditions caused by liquid organic solvents for professional use: saturated or unsaturated aliphatic or cyclic liquid hydrocarbons and mixtures thereof; liquid halogenated hydrocarbons; nitrated derivatives of aliphatic hydrocarbons; alcohols; glycols, glycol ethers; ketones; aldehydes; aliphatic and cyclic ethers, including tetrahydrofuran; esters; dimethylformamide and dimethylacetamine; acetonitrile and propionitrile; pyridine; dimethylsulfone and dimethylsulfoxide	

#### Germany

Water hazard class (WGK)	: WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	: Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

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VOC content	: 4 %
Netherlands	
SZW-lijst van kankerverwekkende stoffen SZW-lijst van mutagene stoffen NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid NIET-limitatieve lijst van voor de voortplanting	<ul> <li>ALCOHOL is listed</li> <li>None of the components are listed</li> <li>ALCOHOL is listed</li> <li>ALCOHOL is listed</li> </ul>
giftige stoffen – Ontwikkeling Denmark	
Danish National Regulations	: Pregnant/breastfeeding women working with the product must not be in direct contact with the product

## 15.2. Chemical safety assessment

#### No additional information available

SECTION 16: Other information		
Full text of H- and EUH-statements:		
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Flam. Liq. 2	Flammable liquids, Category 2	
H225	Highly flammable liquid and vapour.	
H312	Harmful in contact with skin.	
H318	Causes serious eye damage.	
H332	Harmful if inhaled.	

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.