

Creation Date 26-Mar-2012 Revision Date 10-Dec-2021 Revision Number 7

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Description: <u>Amplified IDEIA Hp StAR Kit TM TM</u>

Cat No.: K663011-2

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

Recommended Use In vitro diagnostic.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company Oxoid Ltd

Wade Road

Basingstoke, Hants, UK

RG24 8PW

Tel: +44 (0) 1256 841144

EU entity/business name Oxoid Deutschland GmbH

Postfach 10 07 53

D-46483 Wesel GERMANY

Tel: + 49 (0) 281 1520 Fax: 49 (0) 281 1521

E-mail address mbd-sds@thermofisher.com

1.4. Emergency telephone number

Chemtrec US: (800) 424-9300 Chemtrec EU: 001-703-527-3887 Chemtrec China: 400 120 4937

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP Classification - Regulation (EC) No 1272/2008

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

Based on available data, the classification criteria are not met

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Environmental hazards

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

2.2. Label elements

Signal Word None

Hazard Statements

Precautionary Statements

2.3. Other hazards

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

	Component	CAS No	EC No	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Г	STOP SOLUTION -	7664-93-9	EEC No. 231-639-5	4.5	Skin Corr. 1A (H314)
	Sulphuric acid				Eye Dam. 1 (H318)
Г	POSITIVE CONTROL -	329-98-6	EEC No. 206-350-2	0.1	Skin Corr. 1B (H314)
	alpha-Toluenesulfonyl fluoride				Eye Dam. 1 (H318)
					Acute Tox. 3 (H301)

Component	Specific concentration limits (SCL's)	M-Factor	Component notes
STOP SOLUTION -	Eye Irrit. 2 (H319) :: 5%<=C<15%	-	-
Sulphuric acid	Skin Corr. 1A (H314) :: C>=15%		
·	Skin Irrit. 2 (H315) ::		
	5%<=C<15%		

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

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Ingestion Clean mouth with water and drink afterwards plenty of water.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

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

None reasonably foreseeable.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

None under normal use conditions.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Ensure adequate ventilation.

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

Soak up with inert absorbent material. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Do not get in eyes, on skin, or on clothing. Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid ingestion and inhalation.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Keep at temperatures between 2° and 8 °C.

Technical Rules for Hazardous Substances (TRGS) 510 Class 6.1D Storage Class (LGK) (Germany)

7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

List source(s): **EU** - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC **UK** - EH40/2005 Work Exposure Limits, Third edition. Published 2018. **IRE** - 2018 Code of Practice for the Chemical Agents Regulations, Schedule 1. Published by the Health and Safety Authority

Component	The United Kingdom	European Union	Ireland
STOP SOLUTION -	STEL: 0.15 mg/m ³ 15 min	TWA: 0.05 mg/m ³ (8h)	TWA: 0.05 ppm 8 hr.
Sulphuric acid	TWA: 0.05 mg/m ³ 8 hr		STEL: 0.15 ppm 15 min

Biological limit values

List source(s):

Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

N-Methyl-2-pyrrolidone (NMP) - 14.4mg/m3 (Dermal), 4.8mg/kg/day (Inhalation); See table for values

Со	mponent	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Sulp	SOLUTION - ohuric acid -93-9 (4.5)	DNEL = 0.1mg/m ³		DNEL = 0.05mg/m ³	

Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	I	Water Intermittent Microorganisms in Soil ((Agriculture)
		sediment	sewage treatment	
STOP SOLUTION -	PNEC =	PNEC =	PNEC = 8.8mg/L	

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Sulphuric acid 7664-93-9 (4.5)	0.0025mg/L	0.002mg/kg		
7664-93-9 (4.5)		sediment dw		

Component	Marine water	Marine water sediment	Marine water intermittent	Food chain	Air
STOP SOLUTION -	PNEC =	PNEC =			
Sulphuric acid	0.00025mg/L	0.002mg/kg			
7664-93-9 (4.5)		sediment dw			

8.2. Exposure controls

Engineering Measures

Use only under a chemical fume hood. Avoid exceeding of the given occupational exposure limits. Wash hands before breaks and immediately after handling the product. Ensure that eyewash stations and safety showers are close to the workstation location. Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

Eye Protection Goggles (European standard - EN 166)

Hand Protection Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Disposable gloves	See manufacturers	-	EN 374	(minimum requirement)
	recommendations			

Skin and body protection Long sleeved clothing.

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used

and maintained properly

Large scale/emergency use In case of insufficient ventilation, wear suitable respiratory equipment

Small scale/Laboratory use Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

limits are exceeded or if irritation or other symptoms are experienced.

When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State Liquid

Appearance Varies

Odor No information available Odor Threshold No data available

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Liquid

No data available Melting Point/Range **Softening Point** No data available **Boiling Point/Range** Not applicable Flammability (liquid) No data available Flammability (solid,gas) Not applicable

Explosion Limits No data available

Not applicable Method - No information available **Flash Point**

Autoignition Temperature No data available **Decomposition Temperature** No data available На Not applicable No data available Viscosity Water Solubility Soluble in water Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Vapor Pressure No data available **Density / Specific Gravity** No data available

Bulk Density Not applicable Liquid No data available (Air = 1.0)**Vapor Density**

Particle characteristics Not applicable (liquid)

9.2. Other information

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity None known, based on information available

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization does not occur. **Hazardous Polymerization**

None under normal processing. **Hazardous Reactions**

10.4. Conditions to avoid

Incompatible products. Excess heat.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None under normal use conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Product Information Product does not present an acute toxicity hazard based on known or supplied information

(a) acute toxicity;

Oral Based on ATE data, the classification criteria are not met Dermal Based on ATE data, the classification criteria are not met Inhalation Based on ATE data, the classification criteria are not met

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Toxicology data for the components

Component		LD50 Oral	LD50 Dermal	LC50 Inhalation	
	STOP SOLUTION -	LD50 = 2140 mg/kg (Rat)	-	LC50 = 0.375 mg/L (Rat) 4 h	
	Sulphuric acid				
	POSITIVE CONTROL -	200 mg/kg (Mouse)	-	-	
	alpha-Toluenesulfonyl fluoride				

(b) skin corrosion/irritation; Not classified

(c) serious eye damage/irritation; Not classified

(d) respiratory or skin sensitization;

Respiratory No data available Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

The table below indicates whether each agency has listed any ingredient as a carcinogen

Component	EU	UK	Germany	IARC
STOP SOLUTION -				Group 1
Sulphuric acid				·

(g) reproductive toxicity; Not classified

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard; No data available

Symptoms / effects,both acute and No information available. delayed

11.2. Information on other hazards

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity
Ecotoxicity effects

Component	Freshwater Fish	Water Flea	Freshwater Algae
STOP SOLUTION - Sulphuric acid	LC50: > 500 mg/L, 96h static (Brachydanio rerio)	EC50: 29 mg/L/24h	
	(= , ,		

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12.2. Persistence and degradability

Soluble in water, Persistence is unlikely, based on information available. **Persistence**

12.3. Bioaccumulative potential Bioaccumulation is unlikely

The product is water soluble, and may spread in water systems Will likely be mobile in the 12.4. Mobility in soil

environment due to its water solubility. Highly mobile in soils

12.5. Results of PBT and vPvB

assessment

No data available for assessment.

12.6. Endocrine disrupting

properties

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

Persistent Organic Pollutant **Ozone Depletion Potential**

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues/Unused

Products

Dispose of in accordance with federal, state and local regulations. Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and

hazardous waste. Dispose of in accordance with local regulations.

Contaminated Packaging Dispose of in accordance with local regulations. Dispose of this container to hazardous or

special waste collection point.

European Waste Catalogue (EWC) According to the European Waste Catalog, Waste Codes are not product specific, but

application specific.

Waste codes should be assigned by the user based on the application for which the product Other Information

was used. Do not empty into drains.

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

14.1. UN number UN2796 14.2. UN proper shipping name Sulphuric acid

14.3. Transport hazard class(es) 8 14.4. Packing group П

ADR

UN2796 14.1. UN number

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14.2. UN proper shipping name Sulphuric acid

14.3. Transport hazard class(es) 8
14.4. Packing group II

IATA

14.1. UN number UN2796

14.2. UN proper shipping name Sulphuric acid

14.3. Transport hazard class(es) 8 14.4. Packing group II

14.5. Environmental hazards No hazards identified

14.6. Special precautions for user No special precautions required

<u>14.7. Maritime transport in bulk</u> Not applicable, packaged goods <u>according to IMO instruments</u>

SECTION 15: REGULATORY INFORMATION

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

International Inventories

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
STOP SOLUTION -	7664-93-9	231-639-5	-	-	Х	X	KE-32570	X	Х
Sulphuric acid									
POSITIVE CONTROL -	329-98-6	206-350-2	-	-	Х	Х	-	-	-
alpha-Toluenesulfonyl fluoride									

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
STOP SOLUTION - Sulphuric acid	7664-93-9	X	ACTIVE	Х	-	Х	Х	Χ
POSITIVE CONTROL - alpha-Toluenesulfonyl fluoride	329-98-6	Х	ACTIVE	Х	-	-	Х	-

Legend: X - Listed '-' - Not Listed KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

Authorisation/Restrictions according to EU REACH

Component	, ,	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	,
STOP SOLUTION - Sulphuric acid	-	Use restricted. See item 75. (see link for restriction details)	-

https://echa.europa.eu/authorisation-list

https://echa.europa.eu/substances-restricted-under-reach

https://echa.europa.eu/candidate-list-table

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	
STOP SOLUTION - Sulphuric acid	7664-93-9	Not applicable	Not applicable	

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POSITIVE CONTROL -329-98-6 Not applicable Not applicable alpha-Toluenesulfonyl fluoride

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at

Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values

Take note of Directive 94/33/EC on the protection of young people at work

Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work

National Regulations

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

WGK Classification

Water endangering class = 1 (self classification)

Component	Germany - Water Classification (VwVwS)	Germany - TA-Luft Class
STOP SOLUTION -	WGK1	
Sulphuric acid		

Component	Switzerland - Ordinance on the Reduction of Risk from handling of hazardous substances preparation (SR 814.81)	Switzerland - Ordinance on Incentive Taxes on Volatile Organic Compounds (OVOC)	Switzerland - Ordinance of the Rotterdam Convention on the Prior Informed Consent Procedure
STOP SOLUTION - Sulphuric acid 7664-93-9 (4.5)	Prohibited and Restricted Substances		

15.2. Chemical safety assessment

Chemical Safety Assessment/Reports (CSA/CSR) are not required for mixtures

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H315 - Causes skin irritation

H318 - Causes serious eye damage

H301 - Toxic if swallowed

H314 - Causes severe skin burns and eye damage

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances IECSC - Chinese Inventory of Existing Chemical Substances

ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

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TWA - Time Weighted Average

EC50 - Effective Concentration 50%

LD50 - Lethal Dose 50%

Transport Association

ATE - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

IARC - International Agency for Research on Cancer

ICAO/IATA - International Civil Aviation Organization/International Air

MARPOL - International Convention for the Prevention of Pollution from

Predicted No Effect Concentration (PNEC)

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration **PBT** - Persistent, Bioaccumulative, Toxic

ADR - European Agreement Concerning the International Carriage of

Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime

Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Ships

Physical hazards

Health Hazards

Environmental hazards

On basis of test data
Calculation method
Calculation method

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and

hygiene.

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Revision Summary Change to composition, Update to CLP Format.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet

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