

## Information about Compilation of Safety Data Sheets

**Product:** Histofine DAB-2V  
**Manufacturer:** Nichirei Bioscience Inc.  
6-19-20 Tsukiji, Chuo-ku, Tokyo, 104-8402 Japan  
**Article numbers:** 425312F, 425314F

All components of the aforementioned kit had been classified according to Regulation (EC) No. 1907/2006 (REACH) and to Regulation (EC) No. 1272/2008 (GHS/CLP).

For the kit component Reagent A: DAB Solution Concentrate, a Safety Data Sheet has been compiled (enclosure).

For the remaining kit components Reagent B: DAB Buffer, no Safety Data Sheet is required after classifications according to the Regulation (EC) No. 1907/2006 (REACH) and the Regulation (EC) No. 1272/2008 (GHS/CLP).

When handling the kit components, the general and specific safety precautions for laboratories and the corresponding directives have to be followed.

Date of issue: March 2023

**medac**

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Attachment

**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 03.03.2023

Version number 4 (replaces version 3)

Revision: 03.03.2023

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** N-Histofine DAB-2V, Reagent A: DAB Solution Concentrate**Article number:** 425312F, 425314F, 495316F**Registration number**

This product is a mixture (see chapter 3). Registration number(s) is/are not available for this substance/these substances as the substance(s) or its/their use are exempted from registration according to Article 2 UK REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

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

Relevant identified uses:

For in vitro diagnosis.

Uses advised against:

No further relevant information available.

**Sector of Use** SU20 Health services**Product category** PC21 Laboratory chemicals**Process category** PROC15 Use as laboratory reagent**Application of the substance / the mixture**

Immunochemical reagent for detection / auxiliary reagent for in-vitro diagnosis.

**1.3 Details of the supplier of the safety data sheet****Manufacturer/Distributor:**

Manufacturer:

NICHIREI BIOSCIENCES INC.

6-19-20, Tsukiji, Chuo-ku, Tokyo, 104-8402, Japan

Distributor:

medac GmbH

Theaterstrasse 6

22880 Wedel, Germany

Tel.: +49 (0)4103 8006-0

**Informing department:**

Product Safety

productsafety@medac.de

**1.4 Emergency telephone number:**

GifTinformatiionszentrum-Nord, phone: +49 551 19 240 (service in German and English, 24 hours permanently accessible).

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Acute Tox. 4 H332 Harmful if inhaled.

Eye Irrit. 2 H319 Causes serious eye irritation.

Carc. 2 H351 Suspected of causing cancer.

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labeled in accordance with Regulation (EC) No 1272/2008 (GHS/GB CLP).

**Hazard pictograms**

GHS02 GHS07 GHS08

**Signal word** Danger**Hazard-determining components of labelling:**

acetonitrile

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Trade name: N-Histofine DAB-2V, Reagent A: DAB Solution Concentrate

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3,3'-diaminobenzidine hydrochloride

**Hazard statements**

H225 Highly flammable liquid and vapour.

H332 Harmful if inhaled.

H319 Causes serious eye irritation.

H351 Suspected of causing cancer.

**Precautionary statements**

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P280 Wear protective gloves / protective clothing / eye protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

**Additional information:** Restricted to professional users.**2.3 Other hazards****Results of PBT and vPvB assessment****PBT:** Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.**vPvB:** Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.**SECTION 3: Composition/information on ingredients****3.2 Mixtures****3.1. Chemical characterisation: substances** Not applicable. Product is a mixture.**Description:**

Immunochemical reagent / auxiliary reagent

Mixture of the substances listed below plus non-hazardous additions.

**Dangerous components:**

CAS: 75-05-8 EINECS: 200-835-2 Index number: 608-001-00-3 RTECS: AL 7700000	acetonitrile ⚠ Flam. Liq. 2, H225 ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319	25-50%
CAS: 7411-49-6 EINECS: 231-018-9 Index number: 029-215-99-0	3,3'-diaminobenzidine hydrochloride ⚠ Carc. 2, H351 ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2-3%

**Additional information** For the wording of the listed H-phrases please refer to Section 16.**SECTION 4: First aid measures****4.1 Description of first aid measures****General information** First aider: Take care of self-protection.**After inhalation**

Supply fresh air.

In case of symptoms call a physician.

**After skin contact**

Instantly remove contaminated clothes.

Instantly wash with water and soap and rinse thoroughly.

In case of symptoms call a physician.

**After eye contact**

Rinse eyes cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

Instantly consult ophthalmologist.

**After swallowing**

Let rinse out mouth and then drink plenty of water.

Call doctor.

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**Information for doctor**

Show Safety Data Sheet.

Treatment according to symptoms.

**4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.**Danger** No further relevant information available.**4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### SECTION 5: Firefighting measures

**5.1 Extinguishing media****Suitable extinguishing agents** CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet.**For safety reasons unsuitable extinguishing agents** Water with full jet.**5.2 Special hazards arising from the substance or mixture**

Combustible mixture.

Pay attention to flashback.

In the event of fire, development of dangerous fumes or vapours is possible.

Can be released in case of fire:

Carbon monoxide (CO)

Carbon dioxide (CO<sub>2</sub>)Nitrogen oxides (NO<sub>x</sub>)

Hydrogen cyanide (HCN)

Hydrogen chloride (HCl)

**5.3 Advice for firefighters****Protective equipment:**

In case of fire of large quantities:

Stay in the danger area only with self-contained breathing apparatus.

Prevent skin and eye contact by keeping a safe distance or by wearing suitable protective clothing/safety glasses.

**Additional information**

Collect contaminated fire fighting water separately. It must not enter drains.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

### SECTION 6: Accidental release measures

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

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

Advice for emergency responders: Protective equipment: see Section 8.

**6.2 Environmental precautions:** Do not empty into drains.**6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Afterwards clean with water and cleansing agent.

Dispose of the material collected according to respective national regulations.

Ensure adequate ventilation.

**6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

### SECTION 7: Handling and storage

**7.1 Precautions for safe handling**

Observe label precautions.

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Keep containers tightly sealed.  
Open and handle container with care.  
Prevent formation of aerosols.

Ensure good ventilation/exhaustion at the workplace.

### Information about protection against explosions and fires:

Keep away from open flames, hot surfaces and sources of ignition.

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

#### Storage

#### Requirements to be met by storerooms and containers:

Store container tightly closed in cool, properly ventilated location, apart from ignition and heat sources.

Store at +2 °C to +8 °C.

**Information about storage in one common storage facility:** For this mixture no further information available.

#### Further information about storage conditions:

Store in a locked cabinet or with access restricted to technical experts or their assistants.

#### Storage class

Storage class 6.1.C according to the German "Technical Rules for Hazardous Substances (TRGS) 510": Combustible, acute toxic Cat. 3 / toxic or chronic acting hazardous substances.

**7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Components with critical values that require monitoring at the workplace:

#### 75-05-8 acetonitrile

WEL	Short-term value: 102 mg/m <sup>3</sup> , 60 ppm Long-term value: 68 mg/m <sup>3</sup> , 40 ppm
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**DNELs** For these concentrations no relevant information available.

**PNECs** For these concentrations no relevant information available.

**Additional information:** The official lists that were valid during the compilation were used as basis.

### 8.2 Exposure controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See Section 7.

**Appropriate engineering controls** No further data; see Section 7.

#### Individual protection measures, such as personal protective equipment

#### General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.

Avoid contact with eyes, skin and garments.

Do not inhale aerosols.

Remove contaminated clothing immediately.

Do not eat or drink while working.

Keep away from food and beverages.

Wash hands during breaks and at the end of the work.

**Breathing equipment:** No special precautions are necessary if handled correctly.

#### Hand protection

Protective gloves (AQL 1.5).

The breakthrough times stated below base on laboratory test methods which cannot fully simulate working conditions. It is the responsibility of the end user to choose the appropriate gloves for his application. If working with substances or mixtures harmful in contact with skin, check the gloves beforehand for holes and fissures.

#### Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

Product quality must comply with standard EN 374.

**Penetration time of glove material** Penetration time > 120 min.

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**For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**

Product has not been designed for permanent contact.

**For the permanent contact gloves made of the following materials are suitable:**

Product has not been designed for permanent contact.

**For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Product has not been designed for permanent contact.

**As protection from splashes gloves made of the following materials are suitable:**

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

**Eye/face protection** Safety glasses (standard EN 166).

**Body protection:** Protective work clothing.

**Environmental exposure controls** Do not empty into drains.

**Risk management measures** Void.

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

##### General Information

<b>Physical state</b>	liquid
<b>Colour:</b>	colourless
<b>Smell:</b>	odourless
<b>Odour threshold:</b>	No information available.
<b>Melting point/freezing point:</b>	No information available.
<b>Boiling point or initial boiling point and boiling range</b>	For this concentration no information available.
<b>Flammability</b>	No information available.
<b>Lower and upper explosion limit</b>	
<b>Lower:</b>	Not applicable.
<b>Upper:</b>	Not applicable.
<b>Flash point:</b>	< 23 °C
<b>Decomposition temperature:</b>	No information available.
<b>pH</b>	No information available.
<b>Viscosity:</b>	
<b>Kinematic viscosity</b>	No information available.
<b>dynamic:</b>	No information available.
<b>Solubility</b>	
<b>Water:</b>	Miscible
<b>Partition coefficient n-octanol/water (log value)</b>	No information available.
<b>Steam pressure:</b>	No information available.
<b>Density and/or relative density</b>	
<b>Density</b>	No information available.
<b>Relative density</b>	No information available.
<b>Vapour density</b>	No information available.

#### 9.2 Other information

<b>Appearance:</b>	
<b>Form:</b>	liquid
<b>Important information on protection of health and environment, and on safety.</b>	
<b>Self-inflammability:</b>	No information available.
<b>Explosive properties:</b>	Not explosive.
<b>Solvent content:</b>	
<b>Organic solvents:</b>	50 %
<b>Water:</b>	47.5 %
<b>Solids content:</b>	2.5 %
<b>Change in condition</b>	Not applicable.

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**Softening point/range****Oxidising properties**

No information available.

**Evaporation rate**

No information available.

**Information with regard to physical hazard classes****Explosives**

Void

**Flammable gases**

Void

**Aerosols**

Void

**Oxidising gases**

Void

**Gases under pressure**

Void

**Flammable liquids**

Highly flammable liquid and vapour.

**Flammable solids**

Void

**Self-reactive substances and mixtures**

Void

**Pyrophoric liquids**

Void

**Pyrophoric solids**

Void

**Self-heating substances and mixtures**

Void

**Substances and mixtures, which emit flammable gases**

in contact with water

Void

**Oxidising liquids**

Void

**Oxidising solids**

Void

**Organic peroxides**

Void

**Corrosive to metals**

Void

**Desensitised explosives**

Void

### SECTION 10: Stability and reactivity

**10.1 Reactivity** The mixture is chemically not reactive.**10.2 Chemical stability** The product is chemically stable under the indicated storage conditions.**Thermal decomposition / conditions to be avoided:**

No decomposition if used and stored according to the specifications.

**10.3 Possibility of hazardous reactions**

Dangerous reactions are not to be expected when handling the product according to its intended use.

**10.4 Conditions to avoid:**

Heat, flames, sparks.

Avoid contact with incompatible materials.

**10.5 Incompatible materials:**

Acids.

Metals.

Bases.

Oxidising materials.

Combustible materials.

Reducing agents.

**10.6 Hazardous decomposition products:** In case of fire of large quantities: See Section 5.**Additional information:** No further relevant information available.

### SECTION 11: Toxicological information

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

Harmful if inhaled.

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**LD/LC<sub>50</sub> values that are relevant for classification:****75-05-8 acetonitrile**Oral LD<sub>50</sub> 2,730 mg/kg (rat)Dermal LD<sub>50</sub> >2,000 mg/kg (rabbit)**7411-49-6 3,3'-diaminobenzidine hydrochloride**Oral LD<sub>50</sub> 500 mg/kg (rat)**Specific symptoms in biological assay:** No further relevant information available.**Skin corrosion/irritation** Irritations possible.**Serious eye damage/irritation**

Causes serious eye irritation.

**after swallowing:** Mucosal irritations in mouth, pharynx and oesophagus possible.**after inhalation:** Harmful if inhaled.**Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.**Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity**

Suspected of causing cancer.

**Reproductive toxicity** Based on available data, the classification criteria are not met.**STOT-single exposure** Based on available data, the classification criteria are not met.**STOT-repeated exposure** Based on available data, the classification criteria are not met.**Aspiration hazard** Based on available data, the classification criteria are not met.**Other information (about experimental toxicology):** No further relevant information available.**Subacute to chronic toxicity:** No further relevant information available.**Additional toxicological information:** No further relevant information available.**Toxicokinetics, metabolism and distribution** No relevant information available.**Acute effects (acute toxicity, irritation and corrosivity)** No acute toxicity information available for this product.**Sensitisation** No sensitising effect known.**Repeated dose toxicity** No further relevant information available.**11.2 Information on other hazards****Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information****12.1 Toxicity****Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** No further relevant information available.**Other information:** No further relevant information available.**Behaviour in environmental systems:****Components:** No relevant information available.**12.3 Bioaccumulative potential** No relevant information available.**12.4 Mobility in soil** No relevant information available.**12.5 Results of PBT and vPvB assessment****PBT:** PBT assessment not available as chemical safety assessment not required/not conducted.**vPvB:** vPvB assessment not available as chemical safety assessment not required/not conducted.**12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.**12.7 Other adverse effects****Additional ecological information:****General notes:**

Water hazard class 2 (Self-assessment): hazardous for water.

Do not let enter drains.

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

Product residues have to be disposed of according to the Waste Framework Directive as well as national and regional regulations in each the latest versions.

#### Uncleaned packagings:

**Recommendation:** Uncleaned packagings have to be disposed of in the same manner as the product residues.

### SECTION 14: Transport information

#### 14.1 UN number or ID number

ADR, IMDG, IATA UN1648

#### 14.2 UN proper shipping name

ADR 1648 ACETONITRILE mixture  
IMDG, IATA ACETONITRILE mixture

#### 14.3 Transport hazard class(es)

##### ADR



Class 3 (F1) Flammable liquids.  
Label 3

##### IMDG, IATA



Class 3 Flammable liquids.  
Label 3

#### 14.4 Packing group

ADR, IMDG, IATA II

#### 14.5 Environmental hazards:

Marine pollutant: No

#### 14.6 Special precautions for user

Warning: Flammable liquids.  
Kemler Number: 33  
EMS Number: F-E, S-D  
Stowage Category B  
Stowage Code SW2 Clear of living quarters.

#### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

#### Transport/Additional information:

The transport regulations are cited according to international regulations and in the form applicable in Germany (GGVSE). Possible national deviations in other countries are not considered.

##### ADR

Limited quantities (LQ)

Excepted quantities (EQ)

1L

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

Transport category

2

Tunnel restriction code

D/E

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**IMDG****Limited quantities (LQ)**

1L

**Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

**UN "Model Regulation":**

UN 1648 ACETONITRILE MIXTURE, 3, II

### SECTION 15: Regulatory information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Labelling according to Regulation (EC) No 1272/2008** See Section 2.**Directive 2012/18/EU****Named dangerous substances - ANNEX I** Contains none of the listed substances.**Seveso category** P5c FLAMMABLE LIQUIDS**Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t**Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t**National regulations****Information about limitation of use:**

Take note of the directive on the protection of young people at work in the latest version.

Take note of the directive on the safety and health at work for pregnant and breast feeding mothers and workers of childbearing age in the latest version.

**Water hazard class:** Water hazard class 2 (Self-assessment): hazardous for water.**15.2 Chemical safety assessment:** A chemical safety assessment has not been carried out.

### SECTION 16: Other information

All information and recommendations are believed to be correct as of the date of this Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. medac GmbH shall not be held liable for any damage resulting from handling or from contact with the above product.

**Relevant phrases**

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

**Department issuing data specification sheet:** Product Safety**Contact:** productsafety@medac.de**Replaces version from:** 12.05.2018**Reason for alteration:**

General editorial revision.

Update of the classification.

**Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (UK REACH)

PNEC: Predicted No-Effect Concentration (UK REACH)

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LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Flam. Liq. 2: Flammable liquids – Category 2  
Acute Tox. 4: Acute toxicity – Category 4  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
Carc. 2: Carcinogenicity – Category 2  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

**\* Data compared to the previous version altered.**

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