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## Information about Compilation of Safety Data Sheets

**Product: N-Histofine® DAB-3S Kit**  
**Company: Nichirei Biosciences Inc.**  
**Article number: 415192F, 415194F**

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 had been compiled (enclosure).

For the remaining kit components Reagent B: Enhancer Solution Concentrate and Reagent C: Hydrogen Peroxide Solution Concentrate, no Safety Data Sheets are required after classification 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: June 2018

**medac**

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Attachment

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

Printing date 20.06.2018

Version number 2

Revision: 19.06.2018

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** N-Histofine DAB-3S Kit, Reagent A: DAB Solution Concentrate**Article number:** 415192F, 415194F**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 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:**

Giftinformationszentrum-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**

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/CLP).

**Hazard pictograms**

GHS08

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

3,3'-diaminobenzidine hydrochloride

**Hazard statements**

H351 Suspected of causing cancer.

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**Precautionary statements**

P201 Obtain special instructions before use.  
 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.**Labelling of packages where the contents do not exceed 125 ml****Hazard pictograms**

GHS08

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

3,3'-diaminobenzidine hydrochloride

**Hazard statements**

H351 Suspected of causing cancer.

**Precautionary statements**

Restricted to professional users.

P201 Obtain special instructions before use.  
 P308+P313 IF exposed or concerned: Get medical advice/attention.  
 P405 Store locked up.

**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

**3.1. Chemical characterisation: substances** Not applicable. Product is a mixture.**3.2 Chemical characterisation: Mixtures****Description:**

Immunochemical reagent / auxiliary reagent

Mixture of the substances listed below plus nonhazardous additions.

**Dangerous components:**

CAS: 7411-49-6	3,3'-diaminobenzidine hydrochloride	< 2.50%
EINECS: 231-018-9	 Carc. 2, H351	
Index number: 029-215-99-0	 Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

**SVHC** Not applicable.**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.

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**After eye contact**

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

Consult ophthalmologist.

**After swallowing**

Let rinse out mouth and then drink plenty of water.

Call doctor.

**4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

**Information for doctor**

Show Safety Data Sheet.

Treatment according to symptoms.

**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** Product itself does not burn. Use fire fighting measures that suit the environment.

**For safety reasons unsuitable extinguishing agents** For this mixture no limitations of extinguishing agents are given.

**5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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

In case of burning of a larger amount:

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.

Open and handle container with care.

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**Information about protection against explosions and fires:** No special measures required.**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.

Store at +2 °C to +8 °C.

**Information about storage in one common storage facility:** Because of the small quantities not required.**Further information about storage conditions:**

The indications are valid for the whole package.

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

**Storage class** Please see the respective national guidelines.**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

**Additional information about design of technical systems:** No further data; see Section 7.**8.1 Control parameters****Components with critical values that require monitoring at the workplace:**

Not required according to German regulations.

**DNELs** Not applicable.**PNECs** Not applicable.**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.

**Personal protective equipment****General protective and hygienic measures**

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

Avoid contact with the eyes and skin.

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.**Protection of hands:**

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 enduser 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.**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.

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Penetration time &gt; 120 min.

**Eye protection:** Safety glasses (standard EN 166).**Body protection:** Protective work clothing.**Limitation and supervision of exposure into the environment** 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

##### Appearance:

<b>Form:</b>	liquid
<b>Colour:</b>	Pink to purple
<b>Smell:</b>	odourless
<b>Odour threshold:</b>	No information available.

**pH-value:** No information available.

<b>Change in condition</b>	Not applicable.
<b>Melting point/freezing point:</b>	No information available.
<b>Initial boiling point and boiling range:</b>	No information available.

<b>Flash point:</b>	Not applicable.
<b>Inflammability (solid, gaseous)</b>	Not applicable.
<b>Ignition temperature:</b>	Not applicable.
<b>Decomposition temperature:</b>	No information available.
<b>Self-inflammability:</b>	Not self-inflammable.
<b>Explosive properties:</b>	Not explosive.

##### Critical values for explosion:

<b>Lower:</b>	Not applicable.
<b>Upper:</b>	Not applicable.
<b>Oxidising properties</b>	No information available.
<b>Steam pressure:</b>	No information available.
<b>Density</b>	No information available.
<b>Relative density</b>	No information available.
<b>Vapour density</b>	No information available.
<b>Evaporation rate</b>	No information available.

##### Solubility in / Miscibility with

<b>Water:</b>	Miscible
<b>Partition coefficient: n-octanol/water:</b>	No information available.
<b>Viscosity:</b>	
<b>dynamic:</b>	No information available.
<b>kinematic:</b>	No information available.
<b>Solvent content:</b>	
<b>Organic solvents:</b>	0.0 %
<b>Water:</b>	> 97.5 %
<b>Solids content:</b>	< 2.5 %

**9.2 Other information** No further relevant information available.

### SECTION 10: Stability and reactivity

**10.1 Reactivity** For this mixture no relevant information available.

**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 specifications.

**10.3 Possibility of hazardous reactions** For these concentrations no relevant information available.

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**10.4 Conditions to avoid:** No further relevant information available.**10.5 Incompatible materials:** For these concentrations no further relevant information available.**10.6 Hazardous decomposition products:** In case of burning of larger amounts: See Section 5.**Additional information:** No further relevant information available.

### SECTION 11: Toxicological information

**11.1 Information on toxicological effects****Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC<sub>50</sub> values that are relevant for classification:****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.**Primary irritant effect:****Skin corrosion/irritation** Irritations possible.**Serious eye damage/irritation** Irritations possible.**after swallowing:** Mucosal irritations in mouth, pharynx and oesophagus possible.**after inhalation:** Irritations possible.**Respiratory or skin sensitisation** 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.**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)****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.

### 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.**Additional ecological information:****General notes:**

Generally not hazardous for water.

Do not let enter drains.

**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.

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12.6 Other adverse effects No relevant information available.

### 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

ADR, ADN, IMDG, IATA -

#### 14.2 UN proper shipping name

ADR, ADN, IMDG, IATA -

#### 14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA  
Class -

#### 14.4 Packing group

ADR, IMDG, IATA -

#### 14.5 Environmental hazards:

Marine pollutant: No

#### 14.6 Special precautions for user

Not applicable.

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

#### Transport/Additional information:

Not classified as dangerous in the meaning of transport regulations as issued in the latest version.  
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.

#### UN "Model Regulation":

-

### 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.

**REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 9d

#### 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:** Generally not hazardous for water.

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**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 shall not be held liable for any damage resulting from handling or from contact with the above product.

This Safety Data Sheet is valid for the DAB solution concentrate (Reagent A) of the Histofine DAB-3S Kit (article numbers 415192F, 415194F).

**Relevant phrases**

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

**Department issuing data specification sheet:** Product Safety**Contact:** productsafety@medac.de**Replaces version from:** 03.09.2014**Reason for alteration:**

Update of the classification.

Change of manufacturer's address and of article number(s).

General editorial revision.

Change of contact address.

**Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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 (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

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

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