

Doc ID: SDS-0011	Printing Date: December 15, 2021	Revision: C
Trade name	High Contrast DAB	Revision date: December 15, 2021

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

#### 1.1 Product identifier

Trade name	High Contrast DAB
Article number	K055
Components	N-N-Dimethylformamide, 3,3'-Diaminobenzidine Tetrahydrochloride
	Hydrate, Imidazole, Tween-20
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 Diagnostics	
Uses advises against:	
No further relevant information available.	

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

Diagnostic BioSystems, Inc.
6616 Owens Drive
Pleasanton, CA 94588
www.dbiosys.com
Customersupport@dbiosys.com

#### **1.4** *Emergency telephone number*

Phone: + (925) 484-3350 (English) (9:00am - 4:00 pm, Pacific Standard Time)

## **SECTION 2: Hazards Identification**

#### 2.1 Classification of the substance or mixture

COMPONENT 1 (K055C)			
Mixture (N-N-Dimethylformamide and 3,3'-Diaminobenzidine Tetrahydrochloride Hydrate)			
Hazard class	Category	Hazard statements	
Repr.	1B	H360D: May damage the unborn child.	
Muta	2	H341: Suspected of causing genetic defects	



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Carc.	1A	H350: May cause cancer	
COMPONENT 2 (K055B)			
Imidazole			
Hazard class	Category	Hazard statements	
Repr.	1B	H360D: May damage the unborn child.	

#### 2.2 Label elements

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

COMPONENT 1 (K055C)		
Hazard pictograms		
	GHS08	
Signal word	Danger	
Hazard-determining	N-N-Dimethylformamide	
components of	3,3'-Diaminobenzidine Tetrahydrochloride Hydrate	
labelling	Imidazole	
Hazard statements	H341 Suspected of causing genetic defects.	
	H350 May cause cancer.	
	H360D May damage the unborn child.	
Precautionary	P201 Obtain special instructions before use.	
statements	P280a Wear protective gloves / protective clothing / eye protection.	
	P308+P313 If exposed or concerned: Get medical advice / attention.	
	P405 Store locked up.	
Additional	Restricted to professional users.	
information		
EUH statements	None	

COMPONENT 2 (K055B)		
Hazard pictograms		
	GHS08	
Signal word	Danger	
Hazard-determining	Imidazole	
components of		
labelling		
Hazard statements	H360D May damage the unborn child.	



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Precautionary	P201 Obtain special instructions before use.	
statements	P280a Wear protective gloves / protective clothing / eye protection.	
	P308+P313 If exposed or concerned: Get medical advice / attention.	
	P405 Store locked up.	
Additional	Restricted to professional users.	
information		
EUH statements	None	

#### 2.3 Other hazards

#### Results of PBT/vPvB assessment

Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.

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

COMPONENT 1 (K 055C)			
Dangerous components:			
Name	Classification (for pure substances)	Concentration	
N-N-Dimethylformamide CAS: 68-12-2 EINECS: 200-679-5 Index number: 616-001-00-X	Acute Tox. 4; H312, H332 Eye Irrit. 2; H319 Repr. 1B; H360D	Concentration: <5%	
3,3'-Diaminobenzidine Tetrahydrochloride Hydrate CAS: 868272-85-9 EINECS: None Index number: None	Acute Tox. 4; H302 Eye Irrit. 2; H319 Muta. 2; H341 Carc. 1A; H350 Skin Irrit. 2; H315	Concentration: <5%	

COMPONENT 2 (K 055B)		
Dangerous components:		
Imidazole	Acute Tox. 4; H302	Concentration: <0.5%
CAS: 288-32-4	Skin Corr. 1C; H314	
EINECS: 206-019-2	Repr. 1B; H360	
Index number: None		

Results of PBT/vPvB	Substance(s) does/do not meet the criteria for PBT according to	
assessment	Regulation (EC) No 1907/2006, Annex XIII.	
SVHC	None	
Additional information:	For the wording of the listed H-phrases please refer to Section 16.	

## **SECTION 4: First aid measures**



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#### 4.1 Description of first aid measures

If inhaled	Remove victim to fresh air and keep at rest in a position comfortable for
	breathing.
If on skin	Remove contaminated clothing and wash skin thoroughly. Get medical attention.
	Wash clothing and clean shoes thoroughly before reuse.
If in eyes	Thoroughly flush the eyes with large amounts of clean low-pressure water for at
	least 15 minutes, occasionally lifting the upper and lower eyelids. Check for and
	remove any contact lenses. If irritation persists, seek medical attention.
If swallowed	Do NOT induce vomiting unless directed to do so by medical personnel. Never
	give anything by mouth to an unconscious person. Loosen tight clothing such as a
	collar, tie, belt or waistband. Get medical attention if symptoms appear.
Self-protection	No further relevant information available for this mixture.
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#### 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available for this mixture

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

No further relevant information available for this mixture

## **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media	Foam, dry chemical, or carbon dioxide
For safety reason unsuitable	No further relevant information available for this mixture.
extinguishing agents	

#### 5.2 Special hazards arising from the substance or mixture

Hazardous combustion products	Foam, dry chemical, or carbon dioxide
Other information	No further relevant information available for this mixture.

#### 5.3 Advice for firefighters

Wear protective clothing containing self-contained breathing apparatus.

#### **SECTION 6: Accidental release measures**

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

Protective equipment	Ensure adequate ventilation	
	Eye Protection: Wear goggles or safety glasses	
	Hand protection: Wear latex or vinyl gloves	
	Other protective equipment: Use lab coat or apron to prevent contact	
	with eyes, skin and clothing	
Emergency procedures	No further relevant information available for this mixture.	



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**For emergency responders** No further relevant information available for this mixture.

#### 6.2 Environmental precautions

Do not allow to enter sewage system

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

For containmentNo further relevant information available for this mixture.	
For cleaning upComply with applicable waste disposal regulations	
Other information	No further relevant information available for this mixture.

#### 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

Measures to prevent fire	No further relevant information available for this mixture	
Measures to prevent aerosol and dust generation	No further relevant information available for this mixture	
Measures to protect the environment	No further relevant information available for this mixture	
Advice on general occupational hygiene	No further relevant information available for this mixture	

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

Technical measures and storage conditions	Store in a cool, dry, well-ventilated area away
	from incompatible substances. Keep containers
	tightly closed.
Storage class	See 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**

#### 8.1 Control parameters

Additional information about design of technical systems: Use in a well-ventilated place and keep away from heat and open flame.



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Components with critical vales that require monitoring at the workplace:		
N,N-Dimethylformamide		
limit values as workplace exposure limit WEL or	Short-term value: 10ppm, 30mg/m <sup>3</sup>	
other	Long-term value: 5ppm, 15mg/m <sup>3</sup>	
3,3'-Diaminobenzidine Tetrahydrochloride Hydrate		
limit values as workplace exposure limit WEL or	Short-term value: No Data Available	
other	Long-term value: No Data Available	
Imidazole		
limit values as workplace exposure limit WEL or	Short-term value: No Data Available	
other	Long-term value: No Data Available	

#### DNELs

#### N,N-dimethylformamide:

Route of		
Exposure	Systemic	Local
Inhalation	Long-term/Chronic value:	Long-term/Chronic value:
	6mg/m <sup>3</sup>	no hazard identified:
	Short-term/Acute value:	Short-term/Acute value:
	no hazard identified:	no hazard identified
Dermal	Long-term/Chronic value:	Long-term/Chronic value:
	1.1 mg/kg bw/day	no hazard identified:
	Short-term/Acute value:	Short-term/Acute value:
	no hazard identified	no hazard identified
Eyes	N/A	No hazard identified

#### Imidazole:

Route of		
Exposure	Systemic	Local
Inhalation	Long-term/Chronic value:	Long-term/Chronic value:
	10.6 mg/m <sup>3</sup>	medium hazard (no threshold derived)
	Short-term/Acute value:	Short-term/Acute value:
	no hazard identified:	medium hazard (no threshold derived)
Dermal	Long-term/Chronic value:	Long-term/Chronic value:
	1.5mg/kg bw/day	medium hazard (no threshold derived)
	Short-term/Acute value:	Short-term/Acute value:
	no hazard identified	medium hazard (no threshold derived)
Eyes	N/A	No hazard identified

**PNECS** No further information available.

## 8.2 Exposure controls



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Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See Section 7.

Hugiana Maasuras		
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes and skin. Remove	
	contaminated clothing immediately. Do not eat or drink while	
	working. Keep away from food and beverages. Wash hands	
	during brakes and at the end of work.	
Respiratory Protection	Use in well-ventilated laboratory.	
Skin	Disposable medical gloves (AQL 1.5)	
	The breakthrough times started below 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 for gloves: Natural rubber (NR), Nitrile rubber (NBR)	
	Thickness: 0.11 mm, the product quality has to comply with	
	DIN EN 455.	
	Penetration time: > 120 min	
	Product has not been designed for permanent contact.	
Body protection	Wear protective work clothing.	
Eye/face protection	Wear safety glasses (standard EN 166).	

## **SECTION 9: Physical and chemical properties**

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

General information	
Color:	Liquid
Smell:	No information available
Odor threshold:	No information available
Melting point/freezing point:	No information available
Boiling point or initial boiling point and boiling	No information available
range	
Flammability	Not flammable
Lower and upper explosion limit	No information available
Lower:	No information available
Upper:	No information available
Flash point:	No information available
Self-inflammability:	No information available
Decomposition temperature:	No information available
рН	7.5±0.2
Viscosity:	No information available
Kinematic viscosity	No information available



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Dynamic:	No information available
Solubility	No information available
Water:	No information available
Partition coefficient n-octanol/water (log value)	No information available
Steam pressure:	No information available
Density and/or relative density	No information available
Density	No information available
Relative density	No information available
Vapor density	No information available

## 9.2 Other Information

, <b>,</b>		
Appearance:	Liquid	
Form:	Liquid	
Important information on protection of health	No further information available.	
and environment, and on safety.		
Ignition temperature:	Not applicable.	
Explosive properties:	Not explosive.	
Solvent content:	No information available	
Organic solvents:	No information available	
Water:	No information available	
Solids content:	No information available	
Change in condition	Not applicable	
Softening point/range	Not applicable	
Oxidizing properties	Not applicable	
Evaporation rate	No information available	
Information with regard to physical hazard classes		
Explosives	Void	
Flammable gases	Void	
Aerosols	Void	
Oxidizing gases	Void	
Gases under pressure	Void	
Flammable liquids	Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self- heating substances and mixtures	Void	
Substances and mixtures, with emit flammable	Void	
gases in contact with water		
Oxidizing liquids	Void	
Oxidizing solids	Void	
Organic peroxides	Void	



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Corrosive to metals	Void
Desensitized explosives	Void

## Section 10: Stability and Reactivity

#### 10.1 Reactivity

No further relevant information available for this mixture

#### 10.2 Chemical Stability

Stable under recommended storage conditions

#### 10.3 Possibility of Hazardous Reactions

No further relevant information available for this mixture

#### 10.4 Conditions to Avoid

No further relevant information available for this mixture

#### 10.5 Incompatible Materials

Strong Acids Strong Oxidizers Metals and Metallic compounds

#### **10.6 Hazardous Decomposition Products**

No further relevant information available for this mixture.

## **SECTION 11: Toxicological Information**

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

LD/LC <sub>50</sub> values that are rele	are relevant for classification:	
	LC / LD <sub>50</sub> :	Endpoint value:
	Oral	LD50 (Oral) values: 3010 mg/kg bw (Rats)
<b>CAS-No</b> : 68-12-2	58-12-2 Inhalation LC50 (Inhalation): 5 850 mg/m <sup>3</sup> (Rats)	
	Dermal	LD50 (Dermal): 3160 mg/kg bw (Rats)
CAS No: 969272 95 0	LC / LD <sub>50</sub> :	Endpoint value:
<b>CAS-No</b> : 868272-85-9	No data Available	No data Available
	LC / LD <sub>50</sub> :	Endpoint value:
	Oral	LD50 (Oral) values: 970 mg/kg bw (Rats)
CAS-No: 288-32-4	S-No: 288-32-4 Inhalation LC50 (Inhalation): No Data Available	
	Dermal	LD50 (Dermal): No Data Available
Acute toxicity	Category 4	
Skin corrosion/irritation	3,3'-Diaminobenzidine Tetrahydrochloride Hydrate: Category 2	



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	Imidazole: Category 2	
Serious eye damage/irritation	Based on available data, the classification criteria are not meet	
Respiratiory or skin sensitization	Based on available data, the classification criteria are not meet	
Germ cell mutagenicity	Based on available data, the classification criteria are not meet	
Carcinogenicity	3,3'-Diaminobenzidine Tetrahydrochloride Hydrate: Carcinogenic 1A	
Reproductive toxicity	<ul> <li>N,N-dimethylformamide:</li> <li>There are three studies available in humans. Two studies shows a minimum of 165 mg/kg bw causes reproductive toxicity.</li> <li>NOAEL for fetal toxicity of 165 mg/kg bw was determined based teratogenic effects (number of total litter losses by resorption and body weight change at 1500 and 500 mg DMF/kg).</li> <li>A NOAEL for maternal toxicity of 165 mg/kg/bw was determined based on a dose-dependent decrease in body weight gain at 1500 and 500 mg DMF/kg.</li> <li>Imidazole:</li> <li>Imidazole, when tested in the rat according to OECD Guideline 414 at dose levels of 20, 60, and 180 mg/kg bw/d, was developmentally toxic and teratogenic at 180 mg/kg bw/d. The NOAEL for maternal toxicity, developmental toxicity and teratogenicity was 60 mg/kg bw/d.</li> </ul>	
STOT-single exposure	Based on available data, the classification criteria are not meet	
STOT-repeated exposure	Based on available data, the classification criteria are not meet	
Aspiration hazard.	Based on available data, the classification criteria are not meet	
Potential Effects of	Based on available data, the classification criteria are not meet	
Chronic Exposure	e	
Symptoms of	Based on available data, the classification criteria are not meet	
Overexposure		

## 11.2 Information on other hazards

Endocrine disrupting properties	
None	

## **SECTION 12: Ecological Information**

#### 12.1 Toxicity

Aquatic Toxicity: No further relevant information available

#### **12.2** Persistence and Degradability

No further relevant information available



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#### 12.3 Bioaccumulative potential

No further relevant information available

#### 12.4 Mobility in Soil

No further relevant information available

#### 12.5 Results of PBT and vPvB Assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

#### **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

#### **12.7** Other adverse effects

Additional ecological information:

General notes:	
Persistent Organic Pollutant	This product does not contain any known or suspected substance
<b>Ozone Depletion Potential</b>	This product does not contain any known or suspected substance

## **SECTION 13: Disposal Considerations**

#### 13.1 Waste Treatment Methods

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

**Recommendation for uncleaned packaging:** Uncleaned packagings have to be disposes of in the same manner as the product residues

## **SECTION 14: Transport Information**

#### 14.1 UN Number

ADR	N/A
IMDG	N/A
ΙΑΤΑ	N/A

#### 14.2 Un Proper Shipping Name

ADR	Not dangerous goods
IMDG	Not dangerous goods
ΙΑΤΑ	Not dangerous goods

#### 14.3 Transport Hazard Class (es)

ADR Class: N/A	_		
		ADR	Class: N/A



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	Label: N/A
	Limited Quantities (LQ): N/A
	Excepted Quantities (EQ): N/A
	Maximum net quantity per inner packaging: N/A
	Maximum net quantity per outer packaging: N/A
	Transport category: N/A
	Tunnel restriction code: N/A
IMDG	Class: N/A
	Label: N/A
	Limited Quantities (LQ): N/A
	Excepted Quantities (EQ): N/A
	Maximum net quantity per inner packaging: N/A
	Maximum net quantity per outer packaging: N/A
	Transport category: N/A
IATA	Class: N/A
	Label: N/A

#### 14.4 Packing Group

ADR	N/A
IMDG	N/A
ΙΑΤΑ	N/A

#### 14.5 Environmental Hazards

No

## <u>14.6 Special Precautions for User</u>

Not applicable

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

Not applicable	
Transport/Additional information:	N/A
UN "Model Regulation":	Not regulated

## **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. EU Regulations: Regulation (EC) No. 2037/2000 substances that deplete Ozone layer: None Regulation (EC) No.850/2004 on persistent Organic Pollutants: None Regulation (EC) No. 649/2012 Import and Export of dangerous chemical: None



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EU REACH Candidate List of Substances of very High Concern for Authorization (SVHC): None Regulation (EC) No.1907/2006, REACH Annex XIV Substances Subject to Authorization, as amended: None

**Regulation (EC) No. 1907/2006 Annex XVII Substances subject to restriction on marketing and use:** None

Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens and mutagens at work: Listed

Directive 2012/18/EU named dangerous substances – ANNEX I: None

Directive 96/82/EC (Seveso III): on the control of Major accident hazards involving dangerous substances: None

**EU Regulation No. 166/2006 PRTR (Pollutant Release and transfer Registry) Annex II: Pollutants:** None

**Directive 98/24/EC on the protection of workers from the risks related to chemical agents at Work:** None

#### Water hazard class:

N-N-Dimethylformamide: WGK-2 Imidazole: WGK-2 Diaminobenzidine tetrahydrochloride hydrate: Not Classified

#### 15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out

## SECTION 16: Other Information

This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information of their particular purposes.

**Relevant phrases** 

None

Department issuing data specification sheet: Regulatory Affairs

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