

# APPENDIX 11-MATERIAL SAFETY DATA SHEET

1.08.2017

# FLOW COLOR /

according to Regulation (EC) No. 1907/2006

# 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

# 1.1 Product identifiers

Products name: Flow-Color / ColourFlow

# Colors: Black, Blue, Green, Orange, Pink, Purple, Red, White, Yellow

Producer: ARKONA Laboratorium Farmakologii Stomatologicznej

Nasutów 99 C, 21-025 Niemce, Polska

Application: Dental flowable composite

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

**Flow-Color / ColourFlow** is a composite, light-cure, micro-hybrid dental restorative material. It is designed to fill all classes of dental cavities (I- V according to Black's including all kinds of restorations), in all kinds of teeth (anterior and posterior, milk and permanent) of decay and not decay origin. The material is of flowable consistency, packed into black syringes 1g and 1,5g. It is equipped with a disposable tip.

# 1.3 Details of the supplier of the safety data sheet

Producer: ARKONA Laboratorium Farmakologii Stomatologicznej Nasutów 99 C, 21-025 Niemce, Polska

Telephone : +48 81 470 57 00

E-mail address : <u>biuro@arkonadent.com</u>

1.4 Emergency telephone number

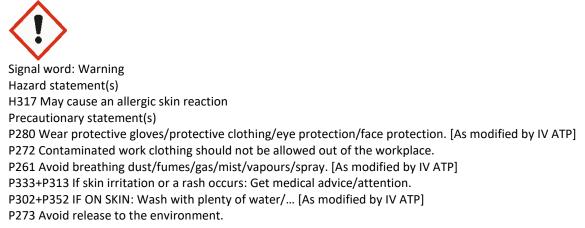
Emergency Phone # : 999, 112

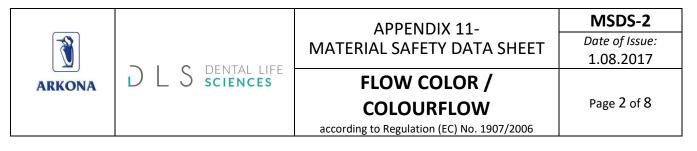
# 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 H317 May cause an allergic skin reaction

# 2.2 Label elements

Labelling according Regulation (EC) No 1272/2008 [CLP] Pictogram





P501 Dispose of contents/ container to an approved waste disposal plant.

# 2.3 Other hazards - none

## **3. COMPOSITION/INFORMATION ON INGREDIENTS**

## 3.1 Substances

Mixture of Bis-GMA, Bisphenol A ethoxylate dimethacrylate, TEGDMA, UDMA, inorganic pigments, bariumborosilicate glasses with initiators, stabilizers and UV absorber.

No	Component	Classification	CAS #
1	Bis-GMA (Bisphenol A glycerolate dimethacrylate)	H318	1565-94-2
2	Ethoxylated Bisphenol A dimethacrylate	Н315, Н317, Н319, Н335	41637-38-1
3	TEGDMA - Triethylene glycol dimethacrylate	Н315, Н319, Н335	109-16-0
4	UDMA (Diurethane dimethacrylate)	H317	72869-86-4
5	Camphorquinone (CQ)		10373-78-1
6	внт	H400, H410	128-37-0

## Hazardous ingredients according to Regulation (EC) No 1272/2008

#### Hazardous ingredients according to Regulation 1999/45/WE

No	Component	Classification	CAS #
1	Bis-GMA (Bisphenol A glycerolate dimethacrylate)	Xi, R41	1565-94-2
2	Ethoxylated Bisphenol A dimethacrylate	Xi, R36/37/38, R43	41637-38-1
3	TEGDMA - Triethylene glycol dimethacrylate	Xi, R36/37/38, R43	109-16-0
4	UDMA (Diurethane dimethacrylate)	Xi, R43	72869-86-4
5	Camphorquinone (CQ)		10373-78-1
6	BHT (2,6-Di-tert-butylo-4- metylofenol)		128-37-0

For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 16.

## 4. FIRST AID MEASURES

## 4.1 Description of first aid measures

#### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. **If inhaled** 



FLOW COLOR /

1.08.2017

Page 3 of 8

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

# In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

DENTAL LIFE

# In case of eye contact

Flush eyes with water as a precaution.

DLS

# If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

The most important known symptoms and effects are described in the labelling and/or in section 11

# **4.3 Indication of any immediate medical attention and special treatment needed** no data available

# **5. FIRE-FIGHTING MEASURES**

# 5.1 Extinguishing media

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
5.2 Special hazards arising from the substance or mixture
no data available
5.3 Advice for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.
5.4 Further information
no data available

# 6. ACCIDENTAL RELEASE MEASURES

# 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

# 6.2 Environmental precautions

Do not let product enter drains.

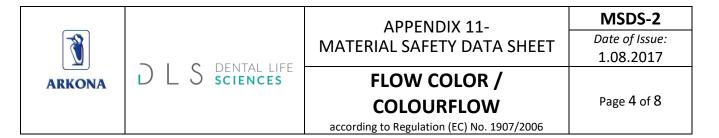
# 6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

## 6.4 Reference to other sections

For disposal see section 13.

# 7. HANDLING AND STORAGE



# 7.1 Precautions for safe handling

Avoid contact with skin, eyes and clothing. Wash hands before and immediately after using this product.

# 7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 3 - 28 °C

## 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

# 8. EXPOSURE CONTROL/PERSONAL PROTECTION

## 8.1 Control parameters

Components with workplace control parameters

## 8.2 Exposure controls

## Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### Personal protective equipment

#### Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

## Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

## **Body Protection**

impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

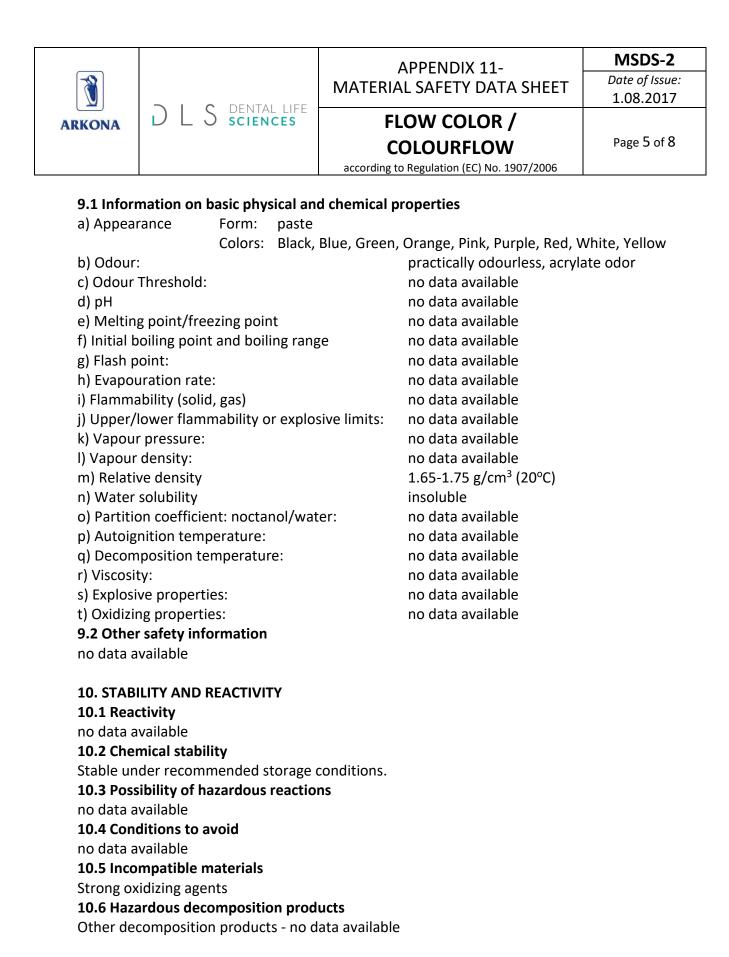
#### **Respiratory protection**

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

## Control of environmental exposure

Do not let product enter drains.

## 9. PHISICAL AND CHEMICAL PROPERTIES



## **11. TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects** Acute toxicity



DLS DENTAL LIFE

# APPENDIX 11-MATERIAL SAFETY DATA SHEET

1.08.2017

# FLOW COLOR / COLOURFLOW

according to Regulation (EC) No. 1907/2006

LD50 Oral - rat - 5000 mg/kg Skin corrosion/irritation Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals Serious eye damage/eye irritation no data available **Respiratory or skin sensitisation** no data available Germ cell mutagenicity no data available Carcinogenicity **Reproductive toxicity** no data available Specific target organ toxicity - single exposure Inhalation - May cause respiratory irritation. Specific target organ toxicity - repeated exposure no data available **Aspiration hazard** 

no data available

# **12. ECOLOGICAL INFORMATION**

12.1 Toxicity
no data available
12.2 Persistence and degradability
no data available
12.3 Bioaccumulative potential
no data available
12.4 Mobility in soil
no data available
12.5 Results of PBT and vPvB assessment
no data available
12.6 Other adverse effects
no data available

# **13. DISPOSAL CONSIDERATIONS**

# **13.1** Waste treatment methods Product



Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

## Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION					
14.1 UN number					
ADR/RID: -	IMDG: -	IATA: -			
14.2 UN proper shipping name					
ADR/RID: Not dangerous goods					
IMDG: Not dangerous goods					
IATA: Not dangerous goods					
14.3 Transport hazard class(es)					
ADR/RID: -	IMDG: -	IATA: -			
14.4 Packaging group					
ADR/RID: -	IMDG: -	IATA: -			
14.5 Environmental hazards					
ADR/RID: no	IMDG Marine pollutant: no	IATA: no			
14.6 Special precautions for user					
no data available					

## **15. REGULATORY INFORMATION**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006. **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture** no data available **15.2 Chemical Safety Assessment** no data available

## **16. OTHER INFORMATION**

## Full text of R-phrases referred to under sections 2 and 3

Xi Irritant R36 Irritating to eyes. R38 Irritating to skin. R36/37/38 Irritating to eyes, respiratory system and skin.

## **Further information**

	DLS DENTAL LIFE	APPENDIX 11- MATERIAL SAFETY DATA SHEET	MSDS-2
			Date of Issue:
			1.08.2017
ARKONA		FLOW COLOR /	
		COLOURFLOW	Page 8 of 8
		according to Regulation (EC) No. 1907/2006	

Copyright **ARKONA Laboratorium Farmakologii Stomatologicznej**. License granted to make unlimited paper copies for internal use only. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. **ARKONA Laboratorium Farmakologii Stomatologicznej** shall not be held liable for any damage resulting from handling or from contact with the above product.

	I approve of its use on:
Prepared by Robert Chilczuk	Joanne Klesente
	1.08.2017