Bray Healthcare Ltd.

SAFETY DATA SHEET

Version 3

Revision Date 27 Jul 2023

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

1.1 Product identifiers

Product name : Caustic Pencil and Caustic Applicator

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

Identified uses : Caustic pencils or applicators consisting of plastic handles bearing small active tips of

various forms of toughened silver nitrate for medicinal use in the treatment of warts,

verrucae, granulation tissue, for cautery and as a medicinal caustic.

1.3 Details of the supplier of the safety data sheet

Manufacturer : Bray Healthcare Ltd

Address : Regal Way

Faringdon Oxfordshire SN7 7BX

UNITED KINGDOM

Telephone : 44 (0) 1367 240736 (Normal Business Hours)

E-mail address : info@bray-healthcare.com

Website : <u>www.bray.co.uk</u>

1.4 Emergency telephone

Emergency Telephone: 44 (0) 1367 240736 (Normal Business Hours with the option to divert the emergency

phone call during non-business hours to available personnel).

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

According to Regulation (EC) No.1272/2008 and European Directive 67/548/EEC (as amended):

Caustic Pencils and Caustic Applicators are classified as articles under both EC/1272/2008 and 67/548/EEC, and therefore not classified as hazardous under EC/1272/2008 or 67/548/EEC. They are also classified as medicinal products so in accordance with Article 2(6)(a) of EC1907/2006 (as amended) so the provisions of Title IV and Annex II of the REACH Regulations shall not apply.

The active tip contains silver nitrate fused with potassium nitrate which is corrosive; the tip makes up a small proportion of the overall product. The details within this safety data sheet correspond to the hazardous properties of the tip rather than of the whole article.

The components of the tip are considered to be oxidising agents in their pure form but the bulk product in the form supplied is not classified as an oxidising agent.

2.2 Label elements

The product does not need to be labelled in accordance with EC/1272/2008 or respective national laws.

Page **1** of **8**



2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Article

Caustic pencils and Caustic applicators are classified as articles, contain no substances listed in Annex XIV or substances on the candidate list in accordance with Article 59(10) of the REACH Regulations and therefore not notifiable under EC/1907/2006 and not reportable under Article 31 of EC/1907/2006.

Note: The components below are present within the active tips of the products. 'Concentration in the product' indicated below represent the relative proportions of the active ingredients.

Component	CLP Classification - Regulation	Signal Word	Concentra	Concentration	Type
Identifiers	(EC) No. 1272/2008 [- Labelling	tion	in Article	
Silver Nitrate					
		<u> </u>		1	
	Ox. Sol. 2, H272, Skin Corr. 1B,	Danger			
	H314				
	Eye Dam. 1, H318, Aquatic Acute				
	1, H400 (M=100), Aquatic				
	Chronic 1, H410 (M=1000) [A] O;		Up to	400/ 050/	[4]
	R8, C; R34, N; R50/53		100%	40% - 95%	[A]
	The product is classified as				
	61- hazardous according to				
	1-8 Regulation (EC) 1272/2008 as				
Index-No. 047-0	01- amended [CLP]				
Potassium Nitrate					
CAS N		T , , ,		F0/ 600/	21/2
CAS-No. 77	57-	Warning		5% - 60%	N/A
EC-No. 23	1-8				
Index-No.					
REACH No:					
01-2119488224-35-			Up to		
XXXX	Ox. Sol. 3, O: R8		100%		
				ĺ	

Type: [A] Constituent [B] Impurity [C] Stabilising additive

For the full text of the H statements mention in this section, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

If inhaled



Page 2 of 8

Very unlikely route of exposure. If dust from broken or damaged tips is inhaled move the person into fresh air and if irritation persists seek medical attention.

In case of skin contact

Wash off with soap and plenty of water. If irritation persists seek further medical attention.

These measures are not required when the product is used on the treated area of skin as per the instruction stated in the PIL.

In case of eye contact

May cause mechanical irritation or damage as well as chemical damage. In case of eye contact flush eye thoroughly with plenty of water for at least 15 minutes while seeking immediate medical attention.

If swallowed

Not a likely route of exposure. If exposure occurs, however, seek immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed

The product when handled and used in its intended form poses minimal risk of harm to human health.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water fog or spray, alcohol-resistant foam, dry chemical or carbon dioxide suitable for other any other materials present that may be involved in a fire.

5.2 Special hazards arising from the substance or mixture

None

5.3 Advice for firefighters

Do not breathe decomposition products and fumes. Use approved self-contained breathing apparatus. Wear fire retardant clothing. Do not enter any enclosed or confined fire space without proper protective equipment, including self-contained breathing apparatus Use water spray to cool containers. Prevent runoff from fire control from entering waterways. Large fires should only be dealt with by trained personnel.

5.4 Further information

No data available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use suitable personal protective equipment (refer to Section 8 for details). Avoid breathing vapours or mists. Ensure adequate ventilation.

6.2 Environmental precautions

Do not let product enter drains or watercourses.

6.3 Methods and materials for containment and cleaning up

Place contaminated or expended materials in disposable containers and dispose of in a manner consistent with applicable regulations.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Page 3 of 8



Use in accordance with product instruction sheets. Do not remove caustic tips from pencils or applicators.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool dry place and protect from direct sunlight.

7.3 Specific end use(s)

No data available.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with occupational exposure limits

None

8.2 Exposure controls

Appropriate engineering controls

Use in well ventilated areas. Use mechanical ventilation in poorly ventilated areas.

Personal protective equipment

Eye/face Protection

Not generally necessary if used in accordance with product instructions. If eye contact is possible use equipment for eye protection tested and approved under appropriate standards such as EN 166.

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 good 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. Recommended glove types include Nitrile and Polythene gloves.

Body Protection

Specific protection not likely to be necessary under normal use and operating conditions in accordance with product instructions.

Respiratory Protection

Not likely to be necessary under normal use and operating conditions in accordance with product instructions.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance (Active Caustic tips)

Physical state Solid

Colour white/off white but may turn grey or black on

prolonged exposure to air.

b) Odour None

c) Odour Threshold Not applicable

d) pH Solutions will be slightly acidic.e) Melting point/freezing point Typically about 150 - 200°C

f) Initial boiling point and No data available. Decomposes at high temperatures.

boiling range

g) Flash point Not applicable
h) Evaporation rate No data available
i) Flammability (solid, gas) Non flammable
j) Upper/lower flammability Non-explosive

or explosive limits



k) Vapour pressure No data available

I) Vapour density No data available, will be very low.

m) Relative density No data availablen) Water solubility Very soluble in water.

o) Partition coefficient: No data available, expected to be very low.

(n- octanol/water)

p) Auto-ignition temperature
 q) Decomposition temperature
 r) Viscosity
 No data available
 Not applicable

s) Explosive properties None

t) Oxidizing properties Mild oxidising properties, not classified as an oxidising

agent in accordance with EC/1272/2008 (as amended)

9.2 Other safety information

No data available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reacts with acetylene and ammonia solutions to form unstable explosive compounds.

10.2 Chemical stability

Expected to be Stable at normal temperatures and under recommended storage conditions.

10.3 Possibility of hazardous reactions

None expected under normal conditions.

10.4 Conditions to avoid

Light, moisture and high temperatures.

10.5 Incompatible materials

Acetylene, acrylonitrile, ethanol and ammonia solutions. Avoid contact with combustible materials, reducing agents, phosphorus, sulphur, charcoal powder and magnesium.

10.6 Hazardous decomposition products

No hazardous decomposition products when stored and handled correctly.

SECTION 11: TOXICOLOGICAL INFORMATION (caustic tip material only)

11.1 Information on toxicological effects

Acute toxicity

LD50 (oral) > 2000mg/kg (rat)

LD50 (dermal) > 2000mg/kg (rabbit)

Ingestion can cause chemical burns to mouth, throat and stomach which in severe cases could be fatal if unattended

Skin corrosion/irritation

Primary eye irritant, may cause severe eye damage

Serious eye damage/eye irritation

Primary skin irritant. Uncontrolled exposure in contradiction to product instructions may cause tissue damage, skin burns or ulcerations.

Respiratory or skin sensitisation

No known sensitisation potential.

Page **5** of **8**



Germ cell mutagenicity

No known mutagenic potential.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No known toxic to reproduction potential.

Specific target organ toxicity - single exposure

Not applicable

Specific target organ toxicity - repeated exposure

Not applicable

Aspiration hazard

Not applicable

Potential health effects - Inhalation, ingestion, skin and eyes

Chronic application of large quantities of silver nitrate products to mucous membranes or open wounds may lead to argyria, and accumulation of silver metal and compounds in the connective tissues, resulting in a local or general greyish or blackish-blue appearance.

Signs and Symptoms of Exposure

None when used in accordance with instructions. Symptoms of silver nitrate poisoning include pain in the mouth, throat or stomach, sialorrhoea, diarrhoea, nausea, vomiting, coma or convulsions.

Additional Information

Not available

SECTION 12: ECOLOGICAL INFORMATION (Caustic tip material only)

12.1 Toxicity

Silver Nitrate - Very toxic to aquatic life.

12.2 Persistence and degradability

Persistent in the environment.

12.3 Bioaccumulative potential

Unlikely to possess significant bio accumulative potential.

12.4 Mobility in soil

Solutions will be highly mobile in soil.

12.5 Results of PBT and vPvB assessment

Not expected to meet PBT or vPvB criteria.

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Material is classified as hazardous waste under the Hazardous Waste Regulations 2005 (as amended) and used contaminated articles may be classified as biological waste. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging

Dispose of as an unused product.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: IMDG: IATA:

Not dangerous goods Not dangerous goods Not dangerous goods

Page 6 of 8



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

Additional Information

ADR/RID - The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg

IMDG - The marine pollutant mark is not required when transported in sizes of ≤5 L or ≤5 kg.

IATA - The environmentally hazardous substance mark may appear if required by other transportation regulations.

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

This safety datasheet is exempt from the requirements of Regulation (EC) No. 1907/2006 but follows the principles within Annex II of these regulations as amended by Commission Regulation (EU) 2015/830 - United Kingdom (UK)

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

Health & Safety at Work etc. Act 1974

Control of Substances Hazardous to Health Regulations 2002 (as amended)

Chemicals (Hazard Information and Packaging for Supply) Regulations 2009

Classification, Labelling and Packaging of Substances and Mixtures Regulations 2008 (as amended)

EH40/2005 Workplace Exposure Limits (as amended)

Environmental Protection Act 1990

Hazardous Waste Regulations 2005 (as amended)

15.2 Chemical Safety Assessment

No data available

16 OTHER INFORMATION

Abbreviations and acronyms :					
ATE	Acute Toxicity Estimate	PBT	Persistent, Bioaccumulative and Toxic		
CLP	Classification, Labelling and Packaging Regulation (Regulation (EC) No. 1272/2008]	PNEC	Predicted No Effect Concentration		
DMEL	Derived Minimal Effect Level	RRN	REACH Registration Number		
EUH statement	CLP-specific Hazard statement	vPvB	Very Persistent and Very Bioaccumulativ		

Text of H-code(s) and R-phrase(s) mentioned in Section 3				
H272	May intensify fire, oxidiser	H318	Causes serious eye damage	





H314	Causes severe skin burns and eye damage	H318	Causes serious eye damage
H400	Very toxic to aquatic life	H410	Very toxic to aquatic life with long lasting effects
R8	Contact with combustible material may cause fire	R34	Causes Burns

Recommended restrictions on use

Use in accordance with the manufacturer's technical instructions.

The information in this Safety Data Sheet should be provided to all who will use, handle, store, transport or otherwise be exposed to this product. This information has been prepared for the guidance of plant engineering, operations, management and for people working with or handling these products. This information is believed to be reliable and updated at Revision Date, and represents the best information currently available and known by Bray Healthcare Ltd. (Bray). However, Bray makes no guarantee or warranty, express or implied, with respect to such information and we assume no liability resulting from its use. The information related herein is based on proper handling and anticipated uses and is for the material without chemical additions or alterations. Users should make their own investigations to determine the suitability of the information for their particular purposes. It is the responsibility of the user to undertake a suitable risk assessment/COSHH assessment prior to using this material.

