

100-I53 Standard Refill Red ink

Document Number: HSE 7159F

Date Of Issue: 28/07/2023

Revision Number: 1

Date of Revision: 28/07/2023



This Data Sheet is broken down into components

Standard Pen Refill Housing

The above is manufactured using pigments which are in accordance with: -

- o European Resolution AP (89) 1
- o Recommendation IX of the BfR for colouring plastics
- o EN71-3 Toy regulation
- o EU regulation EU No 2019/1381 amending Regulation EU No 1935/2004
- o Is based on a polymer carrier that is compliant with: -
- o EU regulation EU No 2020/1245 amending and correcting Regulation (EU) No 10/2011
- o EU regulation EU No 2019/1381 amending Regulation EU No 1935/2004

Has been produced according to Regulation 2023/2006/EC on good manufacturing practice for materials and articles intended to come into contact with food, applicable to plastic raw materials.

This compliance statement is based on information supplied by the polymer and pigment manufacturers, migration testing according to Regulation 10/2011, migration modelling and quality control systems in place at Detectamet.

REACH – No substances of very high concern (SVHC) above the 0.1% weight (w/w) threshold limit are present in the materials.

Regulations and Standards

We confirm that the above-mentioned products are suitable for use in contact with all food types and are in conformity with the applicable requirements of the following regulations and standards:

- Regulation (EC) no.1935/2004 on Materials and Articles intended to come into contact with food.
- Commission Regulation (EU) No.10/2011 on Plastic materials intended to come into contact with food including its updates Regulation 1282/2011 and Regulation 1183/2012.
- Regulation (EC) no. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.
- Council of Europe Resolution AP 89/1 on the use of Colorants in Plastic Materials coming into contact with food.
- US FDA 21 CFR 177.1520 (Olefin polymers) with colorants and additives cleared for use through listing in 178.3297 (Colorants for polymers), 178.2010 (antioxidants and/or stabilisers for polymers, or other respective parts of the FDA regulations).

Migration test data obtained under short-term repeat use test conditions (6dm²/kg food) has demonstrated that levels of overall migration and specific migration of additives from these products will not exceed the legal limits with all food types.

Test Simulants	Food Types	Testing Condition
A-C, D1, D2 of Regulation No. 10,2011 for Plastic Materials and Articles in contact with food.	All dry, aqueous, acidic, alcoholic and fatty foods.	2 hours at 70C, Repeat use. Test OM3 of regulation 10/2011

2 hours at 70C, Repeat use. Test OM3 of regulation 10/2011

Dual-use food additives may be present but any migration into food will be minimal.

This compliance statement is based on information supplied by the polymer and pigment manufacturers, migration testing according to Regulation 10/2011, migration modelling and quality control systems in place at Detectamet.

- **General Information**

Maximum use Temperature: 100 °c

Maximum wash Temperature: 121 °c

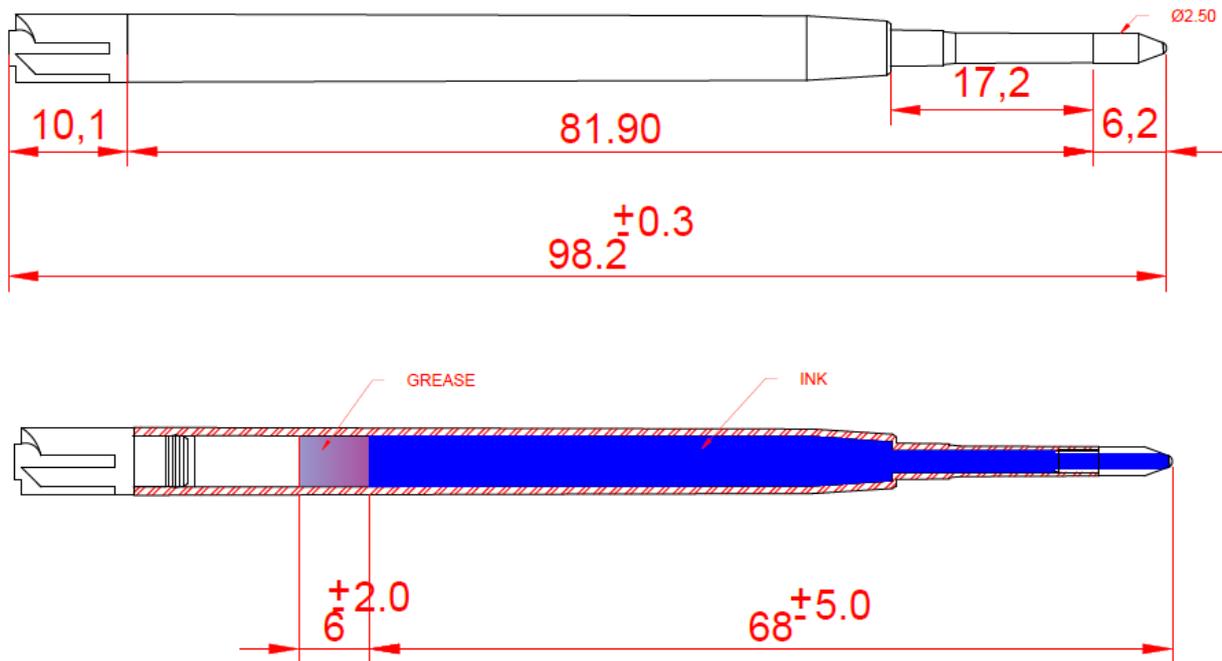
Maximum use Temperature: Do not store at deep freeze temperatures prior to use.

Refill Flight

The above is manufactured using pigments which are in accordance with: -

- o Is manufactured using pigments which are in accordance with
- o European Resolution AP (89) 1
- o Recommendation IX of the BfR for colouring plastics
- o Is manufactured using pigments which are compliant to –
- o EN71-3 Toy regulation
- o Is based on a polymer carrier that is compliant with: -
- o EU regulation EU No 10/2011 as amended

Standard pen refill housing and flight drawing



All dimensions in mm

Refill Ink – Red

1. Identification

Trade name SPL Red

Application of the substance / the mixture Used as inks for sketch pens, fine liners and all kinds of writing instruments.

2. Hazard(s) identification

- **Classification of the substance or mixture**

GHS08 Health hazard



Muta 2.

H341 Suspected of causing genetic defects.

GHS05 Corrosion



Eye Dam 1.

H318 Causes serious eye damage.

GHS09 Environment



Aquatic Chronic 2.

H411 Toxic to aquatic life with long lasting effects.

GHS07



Skin irrit 2.

H315 Causes skin irritation.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

Information concerning particular hazards for human and environment The product has to be labelled due to the calculation procedure of international guidelines.

Classification system The classification was made according to the latest GHS editions of international substances lists and expanded upon from company and literature data.

- **Label elements**

Labelling according to GHS guidelines The product has been classified and marked in accordance with GHS directives on hazardous materials.

Hazard-determining components of labelling Chrysoidine, 2-Phenoxyethanol

Safety phrases Keep out of the reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point. Wear suitable protective clothing, gloves and eye/face protection. If swallowed, seek medical advice immediately and show this container or label.

- **Classification system**

NFPA ratings (scale 0 - 4)



Health = 1

Fire = 1

Reactivity = 0

HMIS-ratings (Scale 0-4)

HEALTH	1
FIRE	1
REACTIVITY	0

Health = 1

Fire = 1

Reactivity = 0

- **Other hazards**

Results of PBT and vPvB assessment

PBT Not applicable.

vPvB Not applicable.

3. Composition/information on ingredients

Chemical characterization: Mixtures

Description Mixture: consisting of the following components.

Dangerous components		
122-99-6	2-Phenoxyethanol	35-42%
100-51-6	Benzyl alcohol	7-9%
509-34-2	3',6'-bis(diethylamino)spiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one	7-9%
495-54-5	Chrysoidine	3-5%
112-80-1	Oleic acid, pure	1-3%
110-98-5	1,1'-oxydipropan-2-ol	0.5-2%
112-90-3	(Z)-octadec-9-enylamine	0.1-1%
Non-Dangerous components		
111-90-0	2-(2-ethoxyethoxy)ethanol	1-3%
9003-39-8	Polyvinyl pyrrolidone	0.1-0.5%
25054-06-2	Formaldehyde, polymer with cyclohexanone	33-38%
61813-75-0	C. I. Solvent Blue 43	0.1-0.5%

4. First aid measures

- Description of first aid measures**

After inhalation Remove person to fresh air. Consult physician.

After skin contact Immediately wash with water and soap and rinse thoroughly.

After eye contact Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing If symptoms persist consult doctor.

Most important symptoms and effects, both acute and delayed Cause skin irritation

Indication of any immediate medical attention and special treatment needed No further relevant information available.

5. Firefighting measures

- Extinguishing media**

Suitable extinguishing agents Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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

- Advice for firefighters**

Protective equipment Wear self-contained breathing apparatus and protective clothing to prevent contact with skin.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.

Environmental precautions Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.

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 disposal information.

7. Handling and storage

Precautions for safe handling Open and handle receptacle with care.

- **Conditions for safe storage, including any incompatibilities.**

Storage

Requirements to be met by storerooms and receptacles Prevent any seepage into the ground. Store in a cool location.

Information about storage in one common storage facility Store away from foodstuffs.

Further information about storage conditions Keep container closed.

Specific end use(s) Used as inks for sketch pens, fine liners and all kinds of writing instruments.

8. Exposure controls/personal protection

Additional information about design of technical systems No further data; see item 7.

- **Control parameters**

Components with limit values that require monitoring at the workplace:	
100-51-6 Benzyl alcohol	
WEEL	Long-term value: 10 ppm
111-90-0 2-(2-ethoxyethoxy)ethanol	
WEEL	Long-term value: 25 ppm

Additional information The lists that were valid during the creation were used as basis.

- **Exposure controls**

Personal protective equipment:

General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the skin. Avoid contact with the eyes and skin.

Breathing equipment In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Protection of hand



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye Protection



Tightly sealed goggles

Body protection Protective work clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties	
General information	
Appearance	Fluid
Form	According to product specification
Colour	Characteristic
Odour	Not determined
Odour threshold	
Change in condition	
Melting point/Melting range	Undetermined
Boiling point/Boiling range	205°C (401°F)
Flash point	101°C (214°F)
Flammability (solid, gaseous)	Not applicable
Ignition temperature	435°C (815°F)
Auto igniting	Product is not self-igniting
Danger of explosion	Product does not present an explosion hazard
Density	Not determined
Solubility in / Miscibility with	
Water	Not miscible or difficult to mix
Other information	No further relevant information available

10. Stability and reactivity

- **Reactivity**

Chemical stability

Thermal decomposition / conditions to be avoided No decomposition if used according to specifications.

Possibility of hazardous reactions No dangerous reactions known.

Conditions to avoid No further relevant information available.

Incompatible materials Strong oxidising agent.

Hazardous decomposition products Carbon oxides.

11. Toxicological information

- **Information on toxicological effects**

Acute toxicity:

LD/LC50 values that are relevant for classification:		
111-90-0 2-(2-ethoxyethoxy)ethanol		
Oral	LD50	6031 mg/kg bw (mouse)
Dermal	LD50	9143 mg/kg bw (rabbit(new Zealand white))
110-98-5 1,1'-oxydipropan-2-ol		
Oral	LD50	14850 mg/kg (Rat)

- **Primary irritant effect**

On the skin CAS No. 112-80-1. Administration of 500 mg of Oleic Acid onto the skin of rabbit caused mild irritating effect.

On the eye CAS No. 122-99-6. The instillation of substance 2 Phenoxy Ethanol at 0.1 mL concentration in rabbit eye caused irritating effect. CAS No. 110-90-0. Administration of Di Propylene Glycol into the eye of rabbit at 500 mg of concentration caused mild irritation.

Sensitization No sensitizing effects known.

Additional toxicological information The product shows the following dangers according to internally approved calculation methods for preparations: irritant.

Carcinogenic categories

IARC (International Agency for Research on Cancer)
None of the ingredients is listed
NTP (National Toxicology Program)
None of the ingredients is listed
OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed

12. Ecological information

- **Toxicity**

Aquatic toxicity As the substance Oleyl Amine (CAS No. 112-90-3) and Chrysodine (CAS No. 495-54-5) having classification as Aquatic Acute 1 and Aquatic chronic 1, contributes only 0.50% and 4% respectively in the final mixture, so the classification of mixture is considered as Aquatic Chronic 2.

Persistence and degradability No further relevant information available.

Bio accumulative potential No further relevant information available.

Mobility in soil No further relevant information available.

Ecotoxic effects

Remark Toxic for fish

- **Additional ecological information**

General notes

Water hazard class 3 (Self-assessment): extremely hazardous for water. Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground. Also poisonous for fish and plankton in water bodies. Toxic for aquatic organisms

Results of PBT and vPvB assessment

PBT Not applicable.

vPvB Not applicable.

Other adverse effects No further relevant information available.

13. Disposable considerations

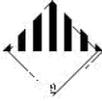
- **Waste treatment method**

Recommendation Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packaging**

Recommendation Disposal must be made according to official regulations.

14. Transport information

UN-Number DOT, ADR, IMDG, IATA	UN3082
UN proper shipping name DOT ADR IMDG IATA	Environmentally hazardous substances, liquid, n.o.s. 3082 environmentally hazardous substances, liquid, n.o.s. (chrysoidine, (Z) -octadec-9-enylamine) Environmentally hazardous substance, liquid, n.o.s. chrysoidine, (Z) -octadec-9-enylamine), marine pollutant. Environmentally hazardous substance, liquid, n.o.s. chrysoidine, (Z) -octadec-9-enylamine)
Transport hazard class(es) DOT  Class Label	9 Miscellaneous dangerous substances and articles 9
ADR, IMDG, IATA  Class Label	9 Miscellaneous dangerous substances and articles 9
Packing group DOT, ADR, IMDG, IATA	III
Environmental hazards	Product contains environmentally hazardous substances: chrysoidine.
Marine pollutant	Yes
Special marking (ADR)	Symbol (fish and tree)
Special marking (IATA)	Symbol (fish and tree)
Special precautions for user	Warning: miscellaneous dangerous substances and articles.
Danger code (Kemler)	90
EMS number	F-A,S-F
Segregation groups	Acids
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

Transport/additional information	
ADR Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30ml Maximum net quantity per outer packaging: 1000ml
IMDG Limited quantities (LQ) Excepted quantities (EQ)	5L Code: E1 Maximum net quantity per inner packaging: 30ml Maximum net quantity per outer packaging: 1000ml
UN "model regulation"	UN3082, environmentally hazardous substance, liquid, n.o.s. chrysoidine, (Z) -octadec-9-enylamine).

15. Regulatory information

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

Sara

Section 355 (extremely hazardous substances)	
None of the ingredients is listed	
Section 313 (specific toxic chemical listings)	
None of the ingredients is listed	
TSCA (Toxic Substances Control Act)	
122-99-6	2-Phenoxyethanol
25054-06-2	Formaldehyde, polymer with cyclohexanone
100-51-6	Benzyl alcohol
509-34-2	3',6'-bis(diethylamino)spiro[isobenzofuran-1(3H), 9'-[9H]xanthene]-3-one
495-54-5	Chrysoidine
111-90-0	2-(2-ethoxyethoxy)ethanol
112-80-1	Oleic acid, pure
110-98-5	1,1'-oxydipropan-2-ol
112-90-3	(Z)-octadec-9-enylamine
9003-39-8	Polyvinyl pyrrolidone

Proposition 65

Chemicals known to cause cancer
None of the ingredients is listed
Chemicals known to cause reproductive toxicity for females
None of the ingredients is listed
Chemicals known to cause reproductive toxicity for males
None of the ingredients is listed
Chemicals known to cause development toxicity
None of the ingredients is listed

Carcinogenic categories

EPA (Environmental Protection Agency)
None of the ingredients is listed
TLV (Threshold Limit Value established by ACGIH)
TLV (ACGIH): 1000ppm
NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients is listed

Product related hazard information The product has been classified and marked in accordance with directives on hazardous materials.

Hazard-determining components of labelling Chrysoidine, 2-Phenoxyethanol

Safety phrases Keep out of the reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point. Wear suitable protective clothing, gloves and eye/face protection. If swallowed, seek medical advice immediately and show this container or label.

- **National regulations**

Other regulations, limitations and prohibitive regulations User to follow national laws and regulations.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Department issuing SDS Product safety department.

Abbreviations and acronyms

ADR: Accord European 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Muta. 2: Germ cell mutagenicity, Hazard Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

Sources

Occupational Safety & Health Administration (OSHA) <https://www.osha.gov/Publications/OSHA3514.html>

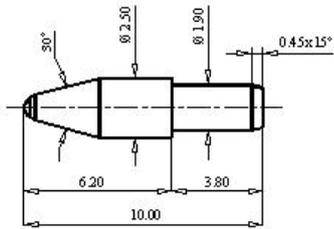
- Data from ECHA dossier of CAS No. 111-90-0 <http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d828fb4-1e4f-6452-e044-00144f67d249/DISS-9d828fb4-1e4f-6452-e044-00144f67d249> DISS-9d828fb4-1e4f-6452-e044-00144f67d249.html

- RTECS data for CAS No. 112-80-1 <http://www.expub.com/Members/Documents/UE54FQYM56KXTDVN807HBSGW3F7DCO.pdf>

- Drugfuture Data for CAS 110-98-5

Standard Refill Tip

1.00mm BNP/TC



It is recommended that prior to and after use, scrapers are cleaned, disinfected & sterilised, as appropriate to their intended use (to minimise risk of microbial Growth and cross contamination, maximising their efficiency and durability).

Model 110.B.01
Patent
Brass/Brp.

No warranty is given or implied with respect to this information or patent infringement. Detectamet Ltd do not accept liability for loss or damage arising from the use of this information. Results are based on a test sample, our general experience and information from our suppliers. Data and results must be confirmed by the buyer by testing for its intended conditions of use.

Helen Morrison
Group Managing Director