



JAN 31 2000

Request for Advisory Opinion 4619 '00 **Wednesday, January 19, 2000**

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with the respect to { Marcode's Industrial Marking Equipment (CIJ) & (DOD) }

- **Issues Involved:** Customers' that have applications, which are in Industrial Food Packing Industries. We have a wide range of product applications that need Identification Codes: Packing Meats, Candies, Cheese, Yogurt, Milk, Potato Chips are just some of the applications. In some cases there are customers that want to print directly onto the edible food or Tea Bags.
- **Statement of Facts and Law:** Marcode wants to conform their inks so that all product applications are in approval for applying ink to product surfaces. We have an ink base that needs to be certified by the USDA and the FDA. Marcode would like to have an Advisor's help, to come up with a documentation process, and provide our ink with a USDA and FDA certified seal of approval. Our current ink base is approved by the European Seal of Safety.

Signature: *Cinzia Schlicksup*

Person of Contact: Cinzia Schlicksup

Mailing Address: Marcode
636 Mendelssohn Ave. N.
Golden Valley, MN 55427

Telephone #: 612-593-1907

00A-0355

AP 1

MarCode, Inc.
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Golden Valley, MN 55427
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**Fax**

JAN 31 2000

To : Ms. Gloria Ortega

From: Cinzia Schlicksup

Comp: FDA

Pages: 1

Fax: 301 827 6870 / Ph. 301 827 6881

Date: January 31, 2000

Re: FOOD GRADE PRINTING INK CC:

Urgent For Review Please Comment Please Reply Confidential

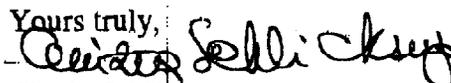
● Comments: Dear Ms. Oriega, Following to our today's phone conversation and our request for advisory opinion on how to get FDA approval for our EC food grade inks, we are submitting for your attention the Statements of Facts and Law.

MarCode Inc. is a US company, incorporated in Minnesota in April 1996. We are importers of industrial marking and coding equipment (ink jet printers) manufactured in Europe by our mother company, Zanasi Fratelli of Italy. Our equipment prints dates, codes, names, logos and barcodes on food and other products packaging. We have been requested by some of our customers to provide them with FDA Approved Food grade ink to print directly on food (i.e. eggs, cheese), or on packaging that may get in contact with food. Our mother company in Europe has supplied us with European Community approved food grade inks that they currently sell in Europe for food applications. We would like to know how we can obtain FDA approval to sell such inks in the United States for printing on food or food packaging that gets in contact with food.

We are attaching for your evaluation the Material Safety Data Sheets and other information on the inks in question.

The undersigned certifies that to the best of my knowledge and belief, this request includes all data, information and views relevant to the matter, whether favorable on or unfavorable to the position of the undersigned, which is the subject of the request.

Yours truly,


Cinzia Schlicksup
Managing Director
MarCode Inc.

Rev.: 000

Issue: 05/99

INK 201 ROSSO A

INK 201 ROSSO A is a red, food grade ink.
It has been designed to meet European approval for contact with food because it's made with food grade components.

It's also suitable for other applications depending on the particular application and country involved. Due to the need for each component to be a listed food approved ingredient in each country where a product is to be sold, each application must be carefully examined.

A dedicated machine should be used with this ink

Printer: JET2000, JET2PLUS

Base: ETHANOL DS A

Packaging:

Ink: 415 ml cartridge

Make-up: MAKE-UP 202 ROSSO A 415 ml cartridge

Wash solution: CLEANER A 1litre bottle, 5 litre bottle

Properties and applications :

The ink is suitable for printing on eggshells, cheese crust, packaging for food and other application in food field. It's adhesion on non porous substrate is weak.

Its drying time is 3-4

Shelf life:

Ink: 12 months from the date of manufacture (see expiry date on the product)

Make-up: 12 months from date of manufacture

Wash solution: 12 months from date of manufacture

Rev.: 000

Issue: 05/99

INK 251 BLU A

INK 201 BLU A is a blue, food grade ink.

It has been designed to meet European approval for contact with food because it's made with food grade components.

It's also suitable for other applications depending on the particular application and country involved. Due to the need for each component to be a listed food approved ingredient in each country where a product is to be sold, each application must be carefully examined.

A dedicated machine should be used with this ink

Printer: JET2000, JET2PLUS

Base: ETHANOL DS A

Packaging:

Ink: 415 ml cartridge

Make-up: MAKE-UP 252 BLU A 415 ml cartridge

Wash solution: CLEANER A 1litre bottle, 5 litre bottle

Properties and applications :

The ink is suitable for printing on eggshells, cheese crust, packaging for food and other application in food field. It's adhesion on not porous substrate is weak.

Its drying time is 3-4

Shelf life:

Ink: 12 months from the date of manufacture (see expiry date on the product)

Make-up: 12 months from date of manufacture

Wash solution: 12 months from date of manufacture



SISTEMI DI SELEZIONE E CODICI D'IDENTIFICAZIONE

Zanasi Fratelli S.r.l. - Via Mercurio, 10 - 41049 Sassuolo (Modena)
Tel. (0536) 88.97.11 - Fax (0536) 88.97.88 - P. I.V.A. 01988040362
Reg. Trib. Mo. 17607 - M/MC 008120 - C.C.I.A.A. Mo. 212219

Sassuolo, 13th October 1999

ZANASI FRATELLI s.r.l. hereby declares that INK 251 BLU A contains Food Edible dyes and that the other constituents are approved for direct contact with food.

Text on coded eggs:

Test 1. The shell and the egg contents were analysed for residual alcohol residues by head space gas chromatography.

Result: No alcohol residues were detected in either boiled or fresh eggs

Test 2. The inner side of the egg shells and the egg itself were examined both visually and thin layers chromatography after extracting the acidified egg with ether.

Result: No evidence of any blue dye residues were detected

Test 3. The coded eggs were tasted against non coded eggs.

Result: No difference in taste was noted

Conclusion: There is no evidence of migration of blue dye, no alcohol residues and no effect on the taste of the eggs.

ZANASI FRATELLI s.r.l.

Gianni Zanasi

The ZANASI logo, identical to the one at the top of the page, with the word "ZANASI" in a bold, sans-serif font next to a stylized grid icon.

A handwritten signature in black ink, appearing to be "Gianni Zanasi", written over the ZANASI logo.

MATERIAL SAFETY DATA SHEET**INK 201 ROSSO A/INK 251 BLU A****PAGE 1 OF 5****1. IDENTIFICATION OF THE SUBSTANCE/PREPARTION AND OF THE COMPANY/UNDERTAKING**

MARCODE, INC.
636 MENDELSSOHN AVENUE NORTH
GOLDEN VALLEY, MN 55427

Phone: 612-593-1907

Emergency phone: Chemtrec 1 (800) 424-9300 For chemical emergencies only.
Or phone to the nearest Medical Facility.

Produce Name: **INK 201 ROSSO A**
INK 251 BLU A

Release: 002 Issue Date 01/07/99

2. COMPOSITION/INFORMATION ON INGREDIENTS

Blend of dyes, additives and resins in alcohol solvents.

Components contribution to hazard:

			CAS	BINECS
Industrial methylated spirits	<85%	Xn: R11-20/22		
Composed of:				
Ethanol	>90%	F; R11	64-17-5	200-578-6
Methanol	3-4%	T; R11-23/25	67-56-1	200-659-6

3. HAZARDS IDENTIFICATION

Highly flammable. Harmful by inhalation and if swallowed.

4. FIRST-AID MEASURES

Never give fluids or nor induce vomiting if patient is unconscious or is having convulsions.

Inhalation

Remove to fresh air if effects occur. If breathing is difficult, oxygen should be administered by qualified personnel. Consult a physician.

Skin Contact

Remove contaminated clothing. Wash off in flowing water or shower. Remove residues with soap and water.

Eye Contact

Irrigate with flowing water immediately and continuously for 15 minutes. Consult medical personnel.

Ingestion

Consult medical personnel. Only induce vomiting if large amounts are ingested.

Note to Physician

No specific antidote. Supportive care. Treatment based on judgement of the physician in response to Reactions of the patient.

5. FIRE-FIGHTING MEASURES**Extinguishing Media**

Water fog, carbon dioxide, alcohol resistant foam, dry chemicals.

MATERIAL SAFETY DATA SHEET**INK 201 ROSSO A/INK 251 BLU A****PAGE 2 OF 5****Hazardous Combustion Products**

Incomplete combustion may lead to the build-up of toxic pyrolysis products. Complete combustion will result in carbon oxides, nitrogen oxides and water.

Protection of Firefighters

Wear positive-pressure self contained breathing apparatus and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots and gloves).

Specific Fire or Explosion Hazards

Highly flammable liquid. Sealed containers exposed to the heat of fire may over-pressurize and explode.

Specific Methods of Firefighting

Fire debris must be disposed of in accordance with local regulations. Do not discharge extinguishing waters into streams, rivers and lakes.

6. ACCIDENTAL RELEASE MEASURES**Personal Precautions**

Wear adequate personal protective equipment, see Section 8, Exposure Controls/Personal Protection. Spills may cause slippery surfaces.

Environmental Precautions

Dike to prevent contamination of ground and surface water, then transfer into closed containers. Recover if possible, or dispose of according to applicable regulations.

Methods of Cleaning Up

Spills should be contained by, and covered with large quantities of sand, earth or any other readily available absorbent material which is then brushed in vigorously to assist absorption. The mixture can then be collected into drums and removed for disposal. Wash area from residues with soap and water and rinse down. Contaminated water should be retained likewise, not being allowed to flow into ground or surface water.

7. HANDLING AND STORAGE**Handling**

Highly flammable: keep away from possible ignition sources. Use non-sparking equipment and tools. No smoking allowed in handling and storage area. Avoid breathing vapours. This product is combustible and may constitute a fire hazard if improperly used or installed.

Storage

Keep container tightly closed. Containers of product should be stored and opened in well ventilated areas away from ignition source.

Storage Temperature and Shelf-Life

The recommended storage temperature is 15-25 deg.C. Storage stability for sealed containers is 12 months.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Occupational exposure limits:**

Substance listed in EX40/92

	Long Term (8 Hrs)		Short Term (10 min)	
	ppm	mg/m ³	ppm	mg/m ³
Industrial methylated spirits	1000	1900	3000	5700

Engineering Controls

Provide general and/or local exhaust ventilation to control airborne levels below the exposure guidelines.

MATERIAL SAFETY DATA SHEET**INK 201 ROSSO A/INK 251 BLU A****PAGE 3 OF 5****Personal Protective Equipment****• Respiratory Protection**

For most conditions, no respiratory protection is needed; however, if handling at elevated temperature Without sufficient ventilation or in presence of aerosol, use an approved air-purifying respirator.

• Skin Protection

Use impervious gloves. Wear clean, long-sleeved, body-covering clothing. After work and before eating, drinking or smoking wash and clean yourself carefully with soap and water. Contaminated clothing should be washed and/or dry cleaned before re-use.

• Eye/Face Protection

Use chemical goggles. If vapour exposure causes eye discomfort, use a full-face respirator. Eye wash fountain should be located in immediate work area.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Red/blue liquid
Odor:	Alcoholic
pH:	not determined
Boiling point/range (deg.C):	80
Melting point/range (deg.C):	not determined
Vapour pressure:	44 mbar a 20 C
Vapour relative density (air=1):	1.59
Relative density (water=1, 20/20 deg.C):	0.9
Viscosity (cP Brookfield LVDT 25°C):	2-4
Water solubility (%):	miscible
LogP (n-octanol/water):	not determined
Volatile substance (%):	not determined
Flash point/range (deg.C):	18
Auto-ignition temp. (deg.C):	360
Flammability-LFL (% vol):	3.3
Flammability-UFL (% vol):	19

10. STABILITY AND REACTIVITY**Chemical Stability**

Stable under normal storage conditions.

Conditions to Avoid

Keep away from ignition sources.

Materials to Avoid

Acids. Oxidizing agents.

Hazardous Decomposition Products

None under normal conditions of storage and use.

11. TOXICOLOGICAL INFORMATION**Acute toxicity****• Ingestion**

The oral LD50 for rats is believed to be >5000 mg/kg. No hazards anticipated from swallowing small amounts incidental to normal industrial handling.

MATERIAL SAFETY DATA SHEET**INK 201 ROSSO A/INK 251 BLU A****PAGE 4 OF 5**

- **Skin Contact**

A single prolonged exposure is not likely to result in the material being absorbed through skin in harmful amounts. The LD 50 for skin absorption in rabbits is believed to be >2000 mg/Kg.

- **Inhalation**

A single brief (minutes) inhalation exposure is not likely to cause adverse effects. Excessive exposure may cause central nervous system effects (headache, dizziness, anesthesia).

- **Eye Contact**

May cause moderate eye irritation. Vapours may irritate eyes.

12. ECOLOGICAL INFORMATION

Assessment largely or completely based on data for similar material(s).

Mobility and Bioaccumulation Potential

No appreciable volatilization from water to air is expected.

Degradation

Ethanol biodegrades rapidly after 15 days in water. 75% of the biodegradation takes place in 20 days in salt water.

Aquatic Toxicity

Acute toxicity to aquatic organisms has not been determined.

13. DISPOSAL CONSIDERATIONS**Disposal**

The generation of waste should be avoided or minimized wherever possible. Burn in an adequate incinerator under carefully controlled conditions in accordance with local and national regulations. Empty containers can only be disposed of when the remaining waste products adhering to the container walls have been removed. Remove all labels.

14. TRANSPORT INFORMATION**Road and Rail**

Proper shipping name: PRINTING INK FLAMMABLE
 Truck - ADR Loaded: 3-5b Empty: II
 Rail - RID/RMP Loaded: 3-5b Empty: II
 UN Number: 1210

Sea

Proper shipping name: PRINTING INK FLAMMABLE
 Sea - IMO/IMDG Class: 3.2 UN Number: 1210 Label: 3
 Packing Group: II IMCO Manual:

Air

Proper shipping name: PRINTING INK FLAMMABLE
 Air - ICAO/IATA Class: 3 UN Number: 1210 Label: 3
 Packing Group: II
 Packing Instructions Passenger: 305
 Packing Instructions Cargo: 307

15. REGULATORY INFORMATION**EEC Classification and User Label Information:**

Classification according to Annex 1 of Council Directive 88/379/EEC (Dangerous Substances Directive)

MATERIAL SAFETY DATA SHEET**INK 201 ROSSO A/INK 251 BLU A****PAGE 5 OF 5**

("EEC Label")

Hazard Symbol:F - Highly Flammable
Xn - Harmful**Risk Phrases:**Highly flammable. (R11)
Harmful by inhalation and if swallowed. (R20/22)**Safety Phrases:**Keep container tightly closed. (S7)
Keep away from sources of ignition - NO SMOKING. (S16)**EINECS Status:**

All components of this product are in compliance with EINECS.

16. OTHER INFORMATION

No other information.

DISCLAIMER: While MarCode, Inc. believes that the data set forth in this sheet is accurate, MarCode, Inc. makes no warranty with respect thereto and expressly disclaims all liability for reliance thereon.

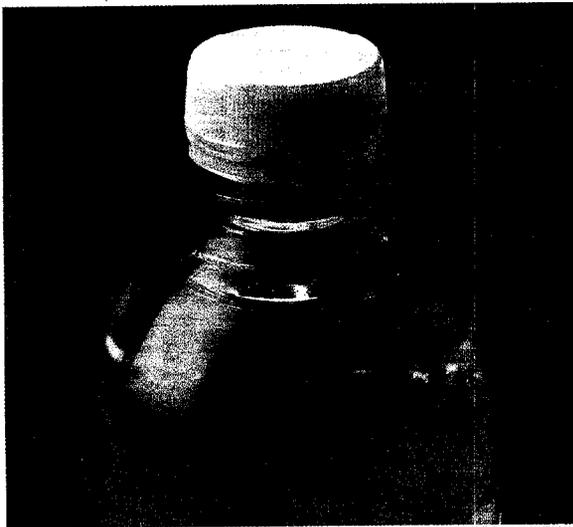
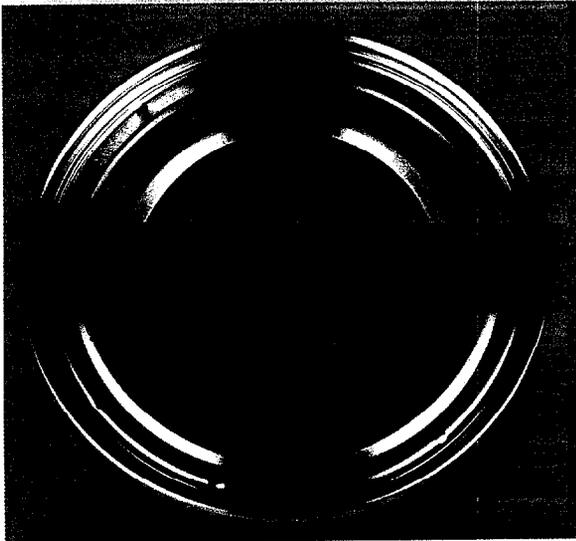
JET2Plus

The Next Generation



MarCode

JET2Plus



Coding Freedom

The JET2Plus offers a new level of flexibility and dependability in generating codes and logos.

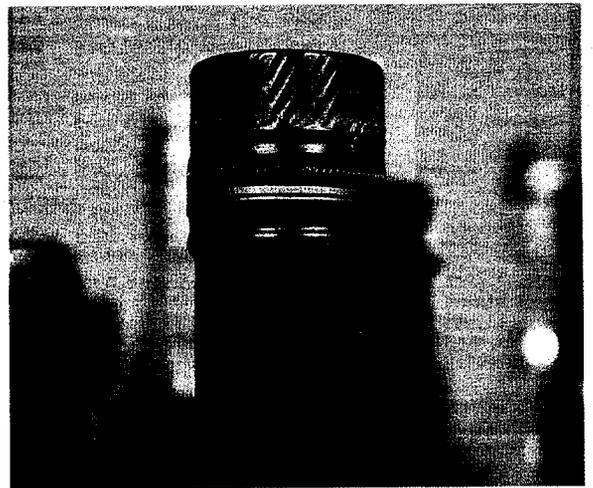
- The **JET2Plus** can store up to 100 messages containing alpha-numeric text, counters, bar codes, automatic "use-by" dates, and logos.
- You can create, edit and store messages and working parameters even while the system is operating, eliminating production delays due to product changeover.
- Six different worldwide bar codes, including UPC-A, can be printed with or without bearer bars and quiet zones, ensuring that your products will be accurately identified whatever their final destination.
- Various standard packing symbols are easily accessible via the keyboard.

The Intelligent Choice

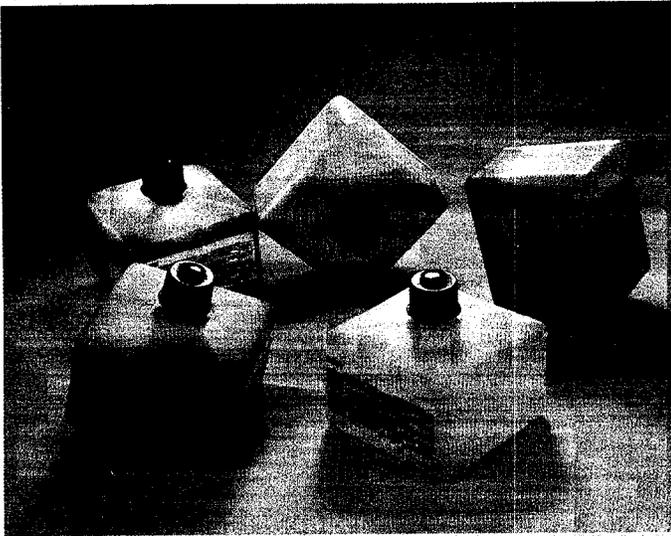
The JET2Plus is the next generation small character printer designed to handle the most demanding applications.

- Positioning the JET2Plus along the production line is extremely easy because it is very compact and does not require compressed air.
- A stainless steel cabinet and printhead, two heavy-duty motors and pumps, a reinforced umbilical cable, and a simple, reliable hydraulic circuit are some of the features that make the **JET2Plus** your best value.
- The **JET2Plus** is Year 2000 ready.
- The integration of hardware, software, hydraulics and electronics allows you to confidently use the **JET2Plus** in the harshest of environments with a guarantee of the highest print quality.

Whatever your application, the JET2Plus is an ideal solution for your marking and coding needs.



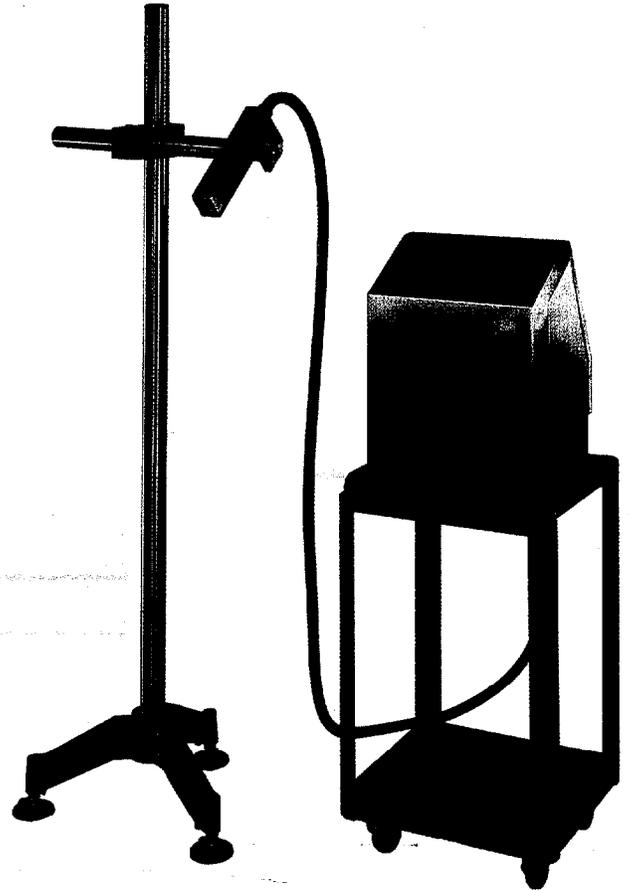
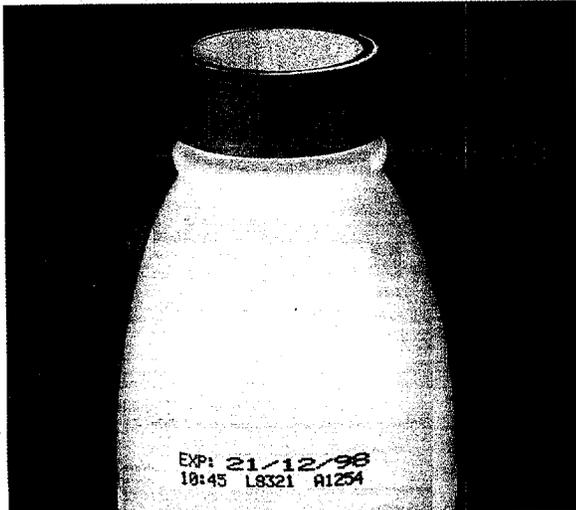
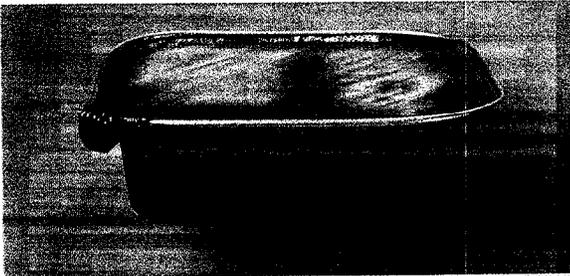
- A full size WYSIWYG graphic display guarantees error-free programming and maximizes your production output.
- Three lines of text and the capability to create standard and customized logos directly from the keyboard of the **JET2Plus**, gives you the fastest and most efficient way to meet your marking and coding needs.



Ink/Make-Up

There are many factors that must be considered in order to identify the correct fluid that will provide you with high-quality, long lasting codes.

- The **JET2Plus** uses several types of inks specifically formulated to meet the requirements of a variety of specific applications.
- MarCode offers a wide range of alcohol, water, and ketone-based inks: standard fast drying, heat-sensitive, pigmented for dark substrates, certified for recyclable containers, food grade, UV-readable and many more, as well as make-up and cleaning fluids.



Total Integration

Total production control is now a basic requirement in today's production facilities. Every piece of equipment that is part of a production line must be able to integrate and operate effectively from a remote location.

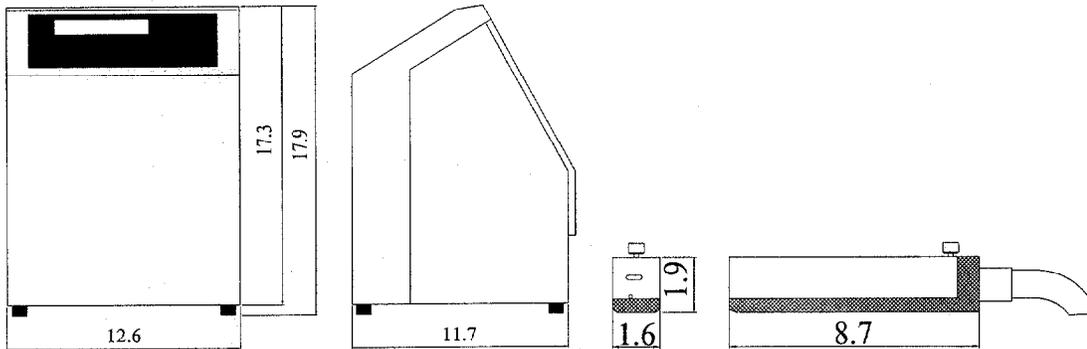
- The RS232 serial interface allows you to control the **JET2Plus** from a remote PC.
 - The unique *Report* function allows you to monitor real-time production levels from a remote location.
- The **JET2Plus** gives you more control over your production.*

Customer Satisfaction

Your productivity is important to us, and we are dedicated to keeping your production lines running as cost-effectively and efficiently as possible. Reducing down time is our goal, and to achieve it MarCode offers extensive operator training, expert technical support and complete maintenance services.

If you have technical questions call our toll-free number (888-MARCODE) and our product experts will provide you with immediate assistance and if necessary dispatch a technician to your location for on-site service and support.

Technical Specifications



Printing characteristics :

- 100 messages with max. 240 char. per message
- Up to 3 lines of text
- Selectable lines spacing
- Font matrix: 5x5, 7x5, 9x7, 16x10
- **Bold** up to 15 times
- Logo creation capability (up to 26 logo)
- Symbologies and special characters

Bar Codes :

- Interleaved 2 of 5 (ITF)
- Code 39
- UPC-A
- 2/5 Industrial
- EAN 13
- EAN 128 (A, B, C)

Line speed :

- 5x5 : 696 ft./min.
- 5x5 twin line : 233 ft./min.
- 5x5 tri-line : 174 ft./min.
- 7x5 : 348 ft./min.
- 7x5 twin line : 174 ft./min.
- 7x5 and 5x5 : 174 ft./min.
- 9x7 : 233 ft./min.
- 9x7 and 5x5 : 174 ft./min.
- 16x10 : 174 ft./min.
- listed speeds are for high quality printing

Character size:

- Selectable from .08" to 1/2"

Counters :

- Incremental counter (1-9 digits)
- Decremental counter (1-9 digits)
- Specific lot number and control of lot quantities
- Automatic shift management (up to 4 shifts)

Field connection :

- RS232C at baud rates selected up to 19.2 kbps
- BCD input

Keyboard/Display:

- 53 keys ketone resistant membrane keyboard
- 240x64 WYSIWYG backlit LCD display

Fluids:

- Various alcohol and ketone based inks and make-ups in 415 ml cartridges
- Cleaning solvents in 1.05 quart bottles and 1.32 gallon containers
- Up to 90 million characters per quart of ink depending on ink type and print setting
- Up to 100 hours per quart of make-up depending on ink type, ambient temperature and print setting

Available accessories:

- External RS422/485 serial interface
- Console and print head stand
- Alert light
- Encoder
- Fiber optics product detectors

Power Supply :

- 85 -130 Vac, 60 Hz single phase, grounded

Temperature/ Humidity range :

- 41° F to 104° F
- 10% to 90% RH without condensation



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1-888-MARCODE (627-2633) • Fax 612-593-1941
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 **MarCode**

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