### **Package Information**

# Tape and Reel and PCB Assembly Information



#### **Tape and Reel Ordering Information**

Power Integrations makes selected surface-mount parts available in tape and reel form for use with automatic pick-and-place equipment. Tape and reel specifications meet or exceed industry standard specification EIA-481.

#### **Ordering Information**

Parts available in tape and reel form can be ordered by placing a tape and reel ordering suffix after the base part number. The ordering suffix is TL.

Base Part #	Tape and Reel Suffix
TNY264G	-TI

Please contact the factory for other options. Minimum order size is 1 reel per line item, and all orders will be in multiples of full reel quantities. The quantity per reel for each package type is shown in Table 1. Power Integrations normal terms and conditions apply.

#### **Electrical Specifications**

Parts are subjected to the Power Integrations standard test flow, after which the parts are loaded into the tape cavities and sealed with a cover tape using standard anti-static handling procedures. The tape and cover are constructed of conductive modified polystyrene, providing a surface resistivity of  $\leq 10^6~\Omega/\text{square}$ . The reel is made of polystyrene with a topical anti-static coating, providing a surface resistivity of  $\leq 10^{11}~\Omega/\text{square}$ .

#### **Physical Specifications**

Physical specifications of the tape, cover, and reel are governed by EIA-481. Physical dimensions of the tapes are given in Figure 2 and Table 2, and physical dimensions of the reels are given in Figure 3 and Table 3.

Daalaaaa	Та	ре	Reel	Pool OTV	
Package	Width (W) Pitch (P)		DIA	Reel QTY	
eSOP-12B	24 mm	16 mm	330 mm	1000	
eSOP-R16B	24 mm	16 mm	330 mm	1000	
HSOP-28	24 mm	12 mm	330 mm	1000	
InSOP-24	24 mm	12 mm	330 mm	2000	
InSOP-L38	32 mm	16 mm	330 mm	1000	
InSOP-T28/-T32	24 mm	12 mm	330 mm	1800	
MinSOP-16A	24 mm	8 mm	330 mm	2000	
SMD-8	16 mm	12 mm	330 mm	1000	
SO-16 / SO-16B	16 mm	12 mm	330 mm	2500	
SO-8* / SO-8C	12 mm	8 mm	330 mm	2500	
SOT-23-6	8 mm	8 mm	330 mm	10000	
TO-263	24 mm	16 mm	330 mm	750	

Table 1. Primary Tape & Reel Dimensions and Reel Quantities. (\*Identical to SOP8)

#### **Packaging for Shipment**

Power Integrations supplies the following information on the side of each reel for ease of product identification:

- · Power Integrations part number (MPN), including orientation suffix
- Assembly date code (D/C)
- Assembly lot identification (LOT)
- Quantity (QTY)
- Tape and reel packing date code (R/D)

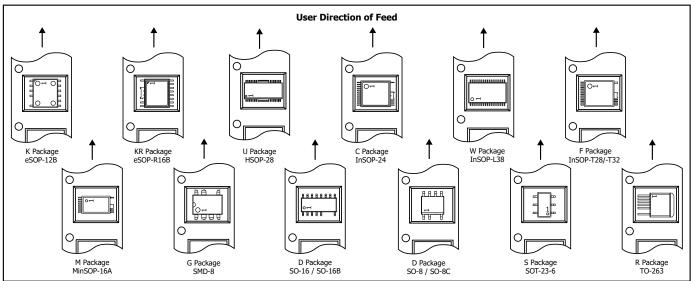


Figure 1. Part Orientation.

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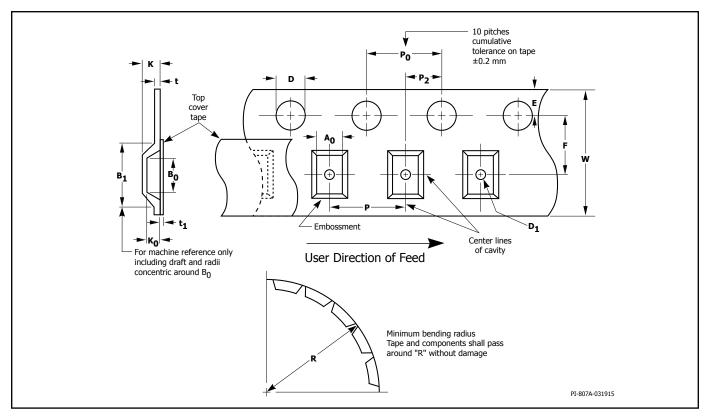


Figure 2. Tape Dimension Index.

Package Type	Tape Size	A <sub>o</sub>	B <sub>o</sub>	B <sub>1</sub>	D	D <sub>1</sub>	E	F	K
eSOP-12B	24 mm	10.27 - 10.77	11.89 - 12.39	13.25 (max)	1.5 - 1.6	1.4 (min)	1.65 - 1.85	11.40 - 11.60	3.22 (max)
eSOP-R16B	24 mm	10.27 - 10.77	11.89 - 12.39	13.25 (max)	1.5 - 1.6	1.4 (min)	1.65 - 1.85	11.40 - 11.60	3.22 (max)
HSOP-28	24 mm	10.7 - 10.9	18.5 - 18.7	18.70 (max)	1.5 -1.6	1.5 (min)	1.65 - 1.85	11.40 - 11.60	3.1 (max)
InSOP-24	24 mm	9.75 - 10.05	11.89 - 12.39	14.25 (max)	1.5 - 1.6	1.5 (min)	1.65 - 1.85	11.40 - 11.60	2.4 (max)
InSOP-L38	32 mm	14.00 - 14.40	20.30 - 20.70	20.70 (max)	1.5 - 1.6	1.5 (min)	1.65 - 1.85	14.10 - 14.30	3.20 (max)
InSOP-T28/-T32	24 mm	9.80 - 10.00	14.00 - 14.20	14.30 (max)	1.5 - 1.6	1.5 (min)	1.65 - 1.85	11.40 - 11.60	2.85 (max)
MinSOP-16A	24 mm	6.0 - 6.20	11.70 - 11.90	12.00 (max)	1.5 - 1.6	1.5 (min)	1.65 - 1.85	11.40 - 11.60	2.20 (max)
SMD-8	16 mm	10.1 - 10.3	10.0 - 10.2	12.1 (max)	1.5 - 1.6	1.5 (min)	1.65 - 1.85	7.40 - 7.60	6.5 (max)
SO-16 / SO-16B	16 mm	6.5 - 6.8	10.3 - 10.6	12.3 (max)	1.5 - 1.6	1.5 (min)	1.65 - 1.85	7.40 - 7.60	2.4 (max)
SO-8* / SO-8C	12 mm	6.5 - 6.7	5.2 - 5.4	5.8 (max)	1.5 - 1.6	1.5 (min)	1.65 - 1.85	5.45 - 5.55	2.2 (max)
SOT-23-6	8 mm	5.20 - 5.40	3.30 - 3.50	N/A	1.5 - 1.6	1.5 - 1.7	1.65 - 1.85	5.40 - 5.60	N/A
TO-263	24 mm	10.9 - 11.1	16.2 - 16.4	16.9 (max)	1.5 - 1.6	1.5 (min)	1.65 - 1.85	11.40 - 11.60	5.9 (max)
Package Type	Tape Size	K <sub>o</sub>	P	P <sub>o</sub>	$P_2$	R	t	t,	W
Package Type eSOP-12B	<b>Tape Size</b> 24 mm	<b>K</b> <sub>o</sub> 2.72 - 3.22	<b>P</b> 15.9 - 16.1	<b>P</b> <sub>0</sub> 3.9 - 4.1	<b>P<sub>2</sub></b> 1.90 - 2.10	<b>R</b> EIA-481	<b>t</b> 0.385 (max)	<b>t<sub>1</sub></b> 0.7 (max)	<b>W</b> 23.7 - 24.3
							_	0.7 (max)	
eSOP-12B	24 mm	2.72 - 3.22	15.9 - 16.1	3.9 - 4.1	1.90 - 2.10	EIA-481	0.385 (max)	0.7 (max)	23.7 - 24.3
eSOP-12B eSOP-R16B	24 mm 24 mm	2.72 - 3.22 2.72 - 3.22	15.9 - 16.1 15.9 - 16.1	3.9 - 4.1 3.9 - 4.1	1.90 - 2.10 3.9 - 4.1	EIA-481 Standard	0.385 (max) 0.385 (max)	0.7 (max) 0.7 (max) .05 (max)	23.7 - 24.3 23.7 - 24.3
eSOP-12B eSOP-R16B HSOP-28	24 mm 24 mm 24 mm	2.72 - 3.22 2.72 - 3.22 3.04 - 3.06	15.9 - 16.1 15.9 - 16.1 12.00	3.9 - 4.1 3.9 - 4.1 3.8 - 4.2	1.90 - 2.10 3.9 - 4.1 1.90 - 2.10	EIA-481 Standard Standard	0.385 (max) 0.385 (max) 0.35 (max)	0.7 (max) 0.7 (max) .05 (max)	23.7 - 24.3 23.7 - 24.3 23.7 - 24.3
eSOP-12B eSOP-R16B HSOP-28 InSOP-24	24 mm 24 mm 24 mm 24 mm	2.72 - 3.22 2.72 - 3.22 3.04 - 3.06 2.10 - 2.45	15.9 - 16.1 15.9 - 16.1 12.00 12.00	3.9 - 4.1 3.9 - 4.1 3.8 - 4.2 3.9 - 4.1	1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 3.9 - 4.1	EIA-481 Standard Standard Standard	0.385 (max) 0.385 (max) 0.35 (max) 0.35 (max)	0.7 (max) 0.7 (max) .05 (max) 0.35 (max)	23.7 - 24.3 23.7 - 24.3 23.7 - 24.3 23.90 - 24.30
eSOP-12B eSOP-R16B HSOP-28 InSOP-24 InSOP-L38	24 mm 24 mm 24 mm 24 mm 32 mm	2.72 - 3.22 2.72 - 3.22 3.04 - 3.06 2.10 - 2.45 2.80 - 3.20	15.9 - 16.1 15.9 - 16.1 12.00 12.00 16.00	3.9 - 4.1 3.9 - 4.1 3.8 - 4.2 3.9 - 4.1 3.8 - 4.2	1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 3.9 - 4.1 1.90 - 2.10	EIA-481 Standard Standard Standard Standard	0.385 (max) 0.385 (max) 0.35 (max) 0.35 (max) 0.35 (max)	0.7 (max) 0.7 (max) .05 (max) 0.35 (max) 0.05 (max) 0.4 (max)	23.7 - 24.3 23.7 - 24.3 23.7 - 24.3 23.90 - 24.30 31.7 - 32.3
eSOP-12B eSOP-R16B HSOP-28 InSOP-24 InSOP-L38 InSOP-T28/-T32	24 mm 24 mm 24 mm 24 mm 32 mm 24 mm	2.72 - 3.22 2.72 - 3.22 3.04 - 3.06 2.10 - 2.45 2.80 - 3.20 2.65 - 2.85	15.9 - 16.1 15.9 - 16.1 12.00 12.00 16.00 12.00	3.9 - 4.1 3.9 - 4.1 3.8 - 4.2 3.9 - 4.1 3.8 - 4.2 3.8 - 4.2	1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 1.90 - 2.10	EIA-481 Standard Standard Standard Standard Standard	0.385 (max) 0.385 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.35 (max)	0.7 (max) 0.7 (max) .05 (max) 0.35 (max) 0.05 (max) 0.4 (max)	23.7 - 24.3 23.7 - 24.3 23.7 - 24.3 23.90 - 24.30 31.7 - 32.3 23.9 - 24.3
eSOP-12B eSOP-R16B HSOP-28 InSOP-24 InSOP-L38 InSOP-T28/-T32 MinSOP-16A	24 mm 24 mm 24 mm 24 mm 32 mm 24 mm 24 mm	2.72 - 3.22 2.72 - 3.22 3.04 - 3.06 2.10 - 2.45 2.80 - 3.20 2.65 - 2.85 2.50 - 2.70	15.9 - 16.1 15.9 - 16.1 12.00 12.00 16.00 12.00 8.0	3.9 - 4.1 3.9 - 4.1 3.8 - 4.2 3.9 - 4.1 3.8 - 4.2 3.8 - 4.2 3.9 - 4.1	1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 1.90 - 2.10 1.90 - 2.10	EIA-481 Standard Standard Standard Standard Standard Standard	0.385 (max) 0.385 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.35 (max)	0.7 (max) 0.7 (max) .05 (max) 0.35 (max) 0.05 (max) 0.4 (max) 0.7 (max)	23.7 - 24.3 23.7 - 24.3 23.7 - 24.3 23.90 - 24.30 31.7 - 32.3 23.9 - 24.3 23.90 - 24.30
eSOP-12B eSOP-R16B HSOP-28 InSOP-24 InSOP-L38 InSOP-T28/-T32 MinSOP-16A SMD-8	24 mm 24 mm 24 mm 24 mm 32 mm 24 mm 24 mm 16 mm	2.72 - 3.22 2.72 - 3.22 3.04 - 3.06 2.10 - 2.45 2.80 - 3.20 2.65 - 2.85 2.50 - 2.70 3.60 - 3.80	15.9 - 16.1 15.9 - 16.1 12.00 12.00 16.00 12.00 8.0 11.9 - 12.1	3.9 - 4.1 3.9 - 4.1 3.8 - 4.2 3.9 - 4.1 3.8 - 4.2 3.9 - 4.1 3.9 - 4.1	1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 1.90 - 2.10 1.90 - 2.10 1.90 - 2.10	EIA-481 Standard Standard Standard Standard Standard Standard 40 (min)	0.385 (max) 0.385 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.400 (max)	0.7 (max) 0.7 (max) .05 (max) 0.35 (max) 0.05 (max) 0.4 (max) 0.7 (max) 0.10 (max)	23.7 - 24.3 23.7 - 24.3 23.7 - 24.3 23.90 - 24.30 31.7 - 32.3 23.9 - 24.3 23.90 - 24.30 15.7 - 16.3
eSOP-12B eSOP-R16B HSOP-28 InSOP-24 InSOP-L38 InSOP-T28/-T32 MinSOP-16A SMD-8 SO-16 / SO-16B	24 mm 24 mm 24 mm 24 mm 32 mm 24 mm 24 mm 16 mm	2.72 - 3.22 2.72 - 3.22 3.04 - 3.06 2.10 - 2.45 2.80 - 3.20 2.65 - 2.85 2.50 - 2.70 3.60 - 3.80 2.10 - 2.40	15.9 - 16.1 15.9 - 16.1 12.00 12.00 16.00 12.00 8.0 11.9 - 12.1 8.0 - 8.3	3.9 - 4.1 3.9 - 4.1 3.8 - 4.2 3.9 - 4.1 3.8 - 4.2 3.9 - 4.1 3.9 - 4.1 4.0 - 4.1	1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 3.9 - 4.1 1.90 - 2.10 1.90 - 2.10 1.90 - 2.10 2.00 - 2.10	EIA-481 Standard Standard Standard Standard Standard Standard 40 (min) EIA-481	0.385 (max) 0.385 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.35 (max) 0.400 (max) 0.35 (max)	0.7 (max) 0.7 (max) .05 (max) 0.35 (max) 0.05 (max) 0.4 (max) 0.7 (max) 0.10 (max) 0.07 (max)	23.7 - 24.3 23.7 - 24.3 23.7 - 24.3 23.90 - 24.30 31.7 - 32.3 23.9 - 24.3 23.90 - 24.30 15.7 - 16.3 15.7 - 16.3

Table 2. Tape Dimensions (in mm).



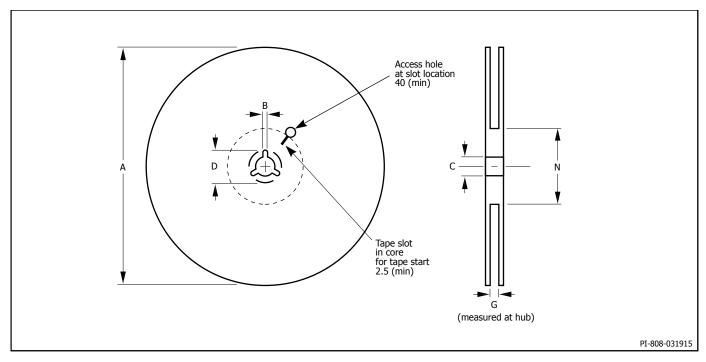


Figure 3. Reel Dimension Index.

Package Type	Tape Size	A	В	С	D	G	N
eSOP-12B	24 mm	332 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	24.4 - 25.4	102 (ref)
eSOP-R16B	24 mm	332 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	24.4 - 25.4	102 (ref)
HSOP-28	24 mm	332 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	24	102 (ref)
InSOP-24	24 mm	332 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	24	102 (ref)
InSOP-L38	32 mm	332 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	32	102 (ref)
InSOP-T28/-T32	24 mm	332 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	24	102 (ref)
MinSOP-16A	24 mm	332 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	24.4 - 25.4	102 (ref)
SMD-8	16 mm	330 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	16	102 (ref)
SO-16 / SO-16B	12 mm	330 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	12	102 (ref)
SO-8* / SO-8C	12 mm	330 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	12	102 (ref)
SOT-23-6	8 mm	328 - 332	2.17 - 2.23	13.00 - 13.50	20.2 (min)	8	98 - 102
TO-263	24 mm	330 (max)	1.5 (min)	12.80 - 13.50	20.2 (min)	24	102 (ref)

Table 3. Reel Dimensions (in mm).

#### **Pb-Free and RoHS Compliant Products**

Power Integrations is committed to environmental, health and safety excellence and is actively complying with regulatory requirements regarding the removal of hazardous materials in manufacturing standards and processes. In response to concerns regarding the environmental impact of lead (Pb), a Pb-free solder finish is now available using 100% matte tin (Sn).

Pb-free packages offered by Power Integrations meet the requirements of the European law on the Restriction of Hazardous Substances (RoHS), which mandates the removal of lead and other hazardous substances cited in the directive. All Pb-free and RoHS compliant products have passed qualification testing for moisture sensitivity, solderability, and whisker growth. Pb-free and RoHS compliant surface mount products also comply with the joint IPC/ JEDEC industry standard on reflow solderability (J-STD-020). More information on soldering is included in Table 4.

RoHS compliant and Pb-free products are designated by an N-suffix at the end of the part number (see the Part Ordering Information section of the product family data sheets).

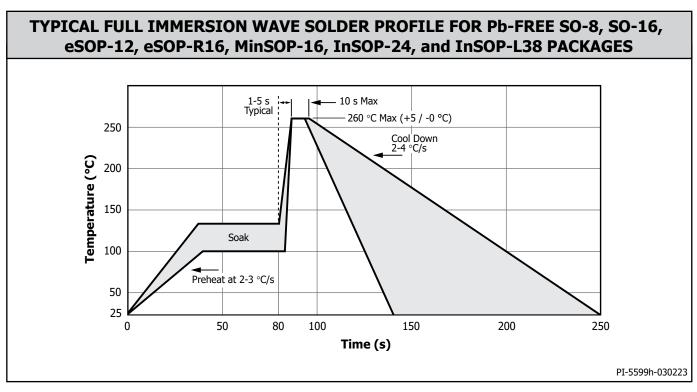
#### **Green Products**

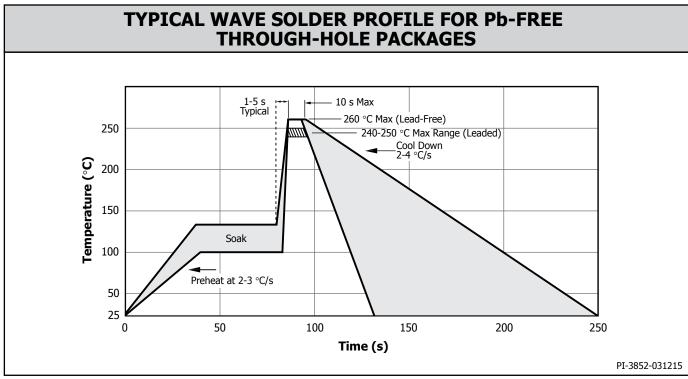
Power Integrations considers GREEN a product RoHS compliant, Pb-Free and Halogen-Free. These products are designed by G-suffix at the end of the part number.

Substance	Upper Limits
Bromine	<900 ppm
Chlorine	<900 ppm
Total Halogen	<1500 ppm
Antimony Trioxide	<1000 ppm

Table 4. Halogen Free Substance Limits.

### **Soldering Temperature Profiles – Wave Soldering**



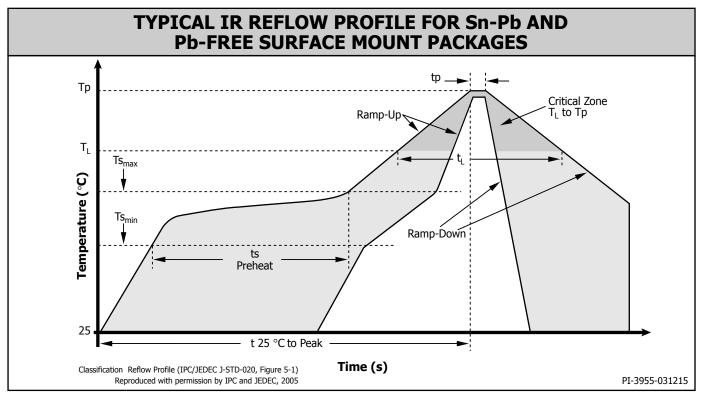


Note 1: Pb-free packages are qualified for Sn-Pb assembly. Sn-Pb packages are not qualified for Pb-free assembly.

## **Wave Soldering Guidelines for InSOP and HSOP Packages**

See Application Note AN-79 Wave Soldering Guidelines for InSOP and HSOP Packages.

## **Soldering Temperature Profiles – IR/Convection Reflow Soldering**



Note 1: Pb-free packages are qualified for Sn-Pb assembly. Sn-Pb packages are not qualified for Pb-free assembly. Refer to Tables 5 and 6 for detailed reflow profile temperatures per package type.

<b>Profile Feature</b>	Sn-Pb Eutectic Assembly	Pb-Free Assembly
Average Ramp-Up Rate (Ts <sub>max</sub> to Tp)	3 °C/second max.	3 °C/second max.
Preheat $\pm$ Temperature Min (Ts <sub>min</sub> ) $\pm$ Temperature Max (Ts <sub>max</sub> ) $\pm$ Time (ts <sub>min</sub> to ts <sub>max</sub> )	100 °C 150 °C 60-120 seconds	150 °C 200 °C 60-180 seconds
Time maintained above: $\pm$ Temperature (T <sub>L</sub> ) $\pm$ Time (t <sub>L</sub> )	183 °C 60-150 seconds	217 °C 60-150 seconds
Peak/Classification Temperature (Tp)	See Table 6	See Table 6
Time within 5 °C of actual Peak Temperature (tp)	10-30 seconds	20-40 seconds
Ramp-Down Rate	6 °C/second max.	6 °C/second max.
Time 25 °C to Peak Temperature	6 minutes max.	8 minutes max.

Table 5. Classification Reflow Profiles (per IPC/JEDEC J-STD-020, Table 5.2)

Note 1: All temperatures refer to topside of the package, measured on the package body surface.

### **Package Information**

## **Soldering Temperature Profiles – IR/Convection Reflow Soldering**

Package Type	Sn-Pb Eutectic Assembly	Pb-Free Assembly
eSOP-12B	235 ℃	260 °C
eSOP-R16B	235 ℃	260 °C
HSOP-28	235 ℃	260 °C
InSOP-24	235 ℃	260 °C
InSOP-L38	220 °C	250 °C
InSOP-T28/-T32	235 ℃	260 °C
MinSOP-16A	235 ℃	260 °C
SMD-8	220 °C	250 °C*
SO-16 / SO-16B	235 ℃	260 °C
SO-8* / SO-8C	235 ℃	260 °C
SOT-23-6	235 ℃	260 °C
TO-263	220 °C	245 °C

<sup>\*</sup>Tolerance: Process compatibility is up to and including the stated classification temperature (this means Peak reflow temperature + 0 °C. For example, 250 + 0 °C) at the rated MSL level.

Note 1: Classification temperatures are in accordance with guidelines set forth in IPC/JEDEC J-STD-020.

### **IR/Convection Reflow Soldering Guidelines**

- Profiles shown are typical and will therefore vary with different soldering systems.
- Density and types of components on the board, size and type of board, solder and flux being used, substrate material being used, equipment type/model and age are factors that can influence the profile.
- Since the melting temperature of solder is higher than the rated temperature of the device, care should be taken that the device will get as little exposure as possible at the high temperature. Not doing so increases possibility of a device failure.
- 4. Limit high temperature exposure only to single side or one time and mostly to the leads area only.
- Upon completion of soldering, gradual natural cooling should be observed for a minimum of three minutes. Using forced cooling will increase temperature gradient which increases mechanical stress leading to latent failure.

#### **PC Board Cleaning**

Power Integrations does not recommend the use of "no-clean" flux.

Table 6. Peak/Classification Temperature (Tp) for PI Surface Mount Packages.

### **Package Information**

Revision	Notes	Date
V	Updated wave solder profiles.	12/09
W	Page 17, per PCN 09081.	12/09
Χ	Added eDIP-12 package.	03/10
Υ	Added SO-8 package, removed MSL information.	04/10
Z	Updated Note 2 on eSIP-7C, eSIP-7F, eDIP-12 and SO-8C.	06/10
AA	Added eSOP-12 package.	10/10
AB	Added eSIP-7G and eSIP-16B packages.	11/10
AC	Updated eSIP-16B package.	03/11
AD	Updated Table 6 with eSOP-12 package type.	03/11
AE	Added eSIP-16C package.	05/11
AF	Added eDIP-12B and eSOP-12B packages. Removed eDIP-12 and eSOP-12 packages.	10/11
AG	Added eSIP-16K L package and eSOP-12B to PI-5599.	02/12
AH	Added eSIP-16J H package.	09/12
ΑI	Corrected SMD-8 value in column "W" for Table 2.	02/13
AJ	Added eSIP-16D H Package, eSIP-16G L Package, eSIP-16F H Package.	06/13
AK	Updated eSIP-16F H Package.	09/13
AL	Added package identifier table.	11/13
AM	Removed IC packages – refer to data sheets.	05/14
AN	Added new Branding Style.	03/15
AO	Added eSOP-R16B package.	04/16
AP	Added SOT-23-6 package.	05/16
AQ	Noted in Table 1 that SOP8 is identical to SO-8.	08/16
AR	Corrected SOT-23-6 pin package direction in Figure 1.	04/17
AS	Added InSOP-24D package.	09/17
AT	Added wave soldering recommendations.	10/17
AU	Updated Figure 1 R package orientation per PCN-18051, and "Typical Full Immersion Wave Solder Profile" on page 4.	03/18
AV	Corrected Table 1 InSOP-24D pitch error.	04/18
AW	Added InSOP-24D to header text in top figure on page 4.	12/18
AX	Updated Solder Profile Figure PI-5599, Table 6 and removed Wave Soldering Guidelines section. Rearranged layout for pages 4, 5 and 6.	03/19
AY	Added SO-16B package information.	06/19
AZ	Added HSOP-28 package information and corrected Table 6.	09/19
ВА	Added Solder Pad Layout Design Recommendations for Wave Soldering of the InSOP Package and Mounting Guidelines for TO-220 Package, pages 7 and 8.	07/20
BB	Added MinSOP-16A package information.	10/20
BC	Added InSOP-T28/-T32, InSOP-L38 package information.	03/23

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#### **Patent Information**

The products and applications illustrated herein (including transformer construction and circuits external to the products) may be covered by one or more U.S. and foreign patents, or potentially by pending U.S. and foreign patent applications assigned to Power Integrations. A complete list of Power Integrations patents may be found at www.power.com. Power Integrations grants its customers a license under certain patent rights as set forth at www.power.com/ip.htm.

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POWER INTEGRATIONS PRODUCTS ARE NOT AUTHORIZED FOR USE AS CRITICAL COMPONENTS IN LIFE SUPPORT DEVICES OR SYSTEMS WITHOUT THE EXPRESS WRITTEN APPROVAL OF THE PRESIDENT OF POWER INTEGRATIONS. As used herein:

- 1. A Life support device or system is one which, (i) is intended for surgical implant into the body, or (ii) supports or sustains life, and (iii) whose failure to perform, when properly used in accordance with instructions for use, can be reasonably expected to result in significant injury or death to the user.
- 2. A critical component is any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.

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