

## General Description

The AOZ1312 is a member of Alpha and Omega Semiconductor's single-channel power-distribution switch family intended for applications where heavy capacitive loads and short-circuits are likely to be encountered. This device incorporates a 70 mΩ N-channel MOSFET power switch for power-distribution systems. The switch is controlled by a logic enable input. Gate drive is provided by an internal charge pump designed to control the power-switch rise time and fall time to minimize current surges during switching. The charge pump requires no external components and allows operation from supplies as low as 2.7 V.

The AOZ1312 is available in an SO-8 or eMSOP-8 package and is rated over the -40 °C to +85 °C ambient temperature range.

## Features

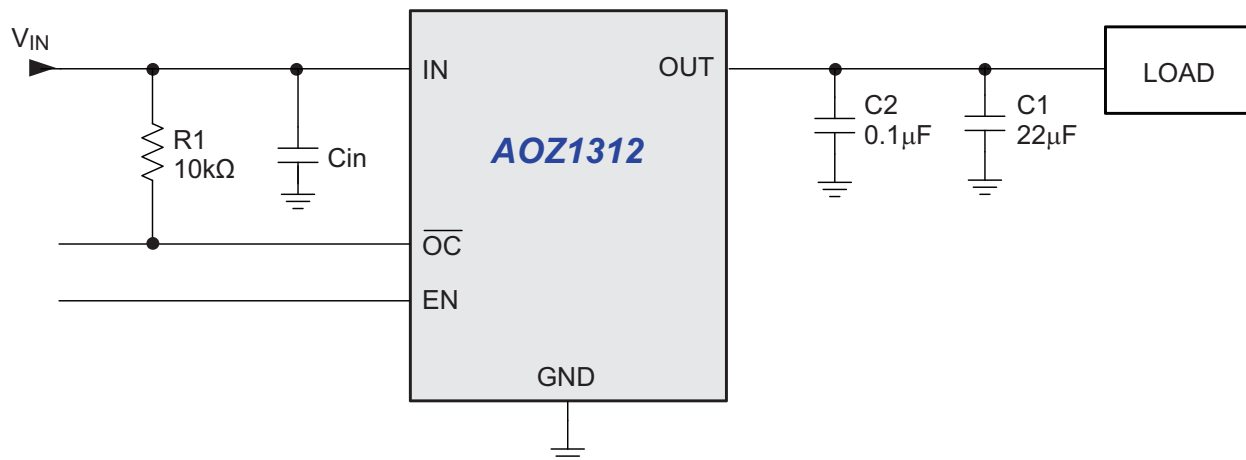
- Typical 70 mΩ (NFET)
- 1.5A maximum continuous current
- Vin range of 2.7 V to 5.5 V
- Open Drain Fault Flag
- Fault Flag deglitched (blanking time)
- Thermal shutdown
- Reverse current blocking
- Packages: SO-8 and eMSOP-8

## Applications

- Notebook Computers
- Desktop Computers



## Typical Application



## Ordering Information

| Part Number  | Maximum Continuous Current |           | Typical Short-circuit Current Limit |           | Enable Setting | Package     | Output Discharge | Environmental                   |
|--------------|----------------------------|-----------|-------------------------------------|-----------|----------------|-------------|------------------|---------------------------------|
|              | Channel 1                  | Channel 2 | Channel 1                           | Channel 2 |                |             |                  |                                 |
| AOZ1341AI    | 1 A                        | 1A        | 1.5 A                               | 1.5 A     | Active Low     | SO-8        | No               | Green Product<br>RoHS Compliant |
| AOZ1341EI    |                            |           |                                     |           |                | EPAD MSOP-8 |                  |                                 |
| AOZ1341AI-1  |                            |           |                                     |           | Active High    | SO-8        |                  |                                 |
| AOZ1341EI-1  |                            |           |                                     |           |                | EPAD MSOP-8 |                  |                                 |
| AOZ1342PI    | 1.5 A                      | 1.5A      | 2 A                                 | 2 A       | Active Low     | EPAD SO-8   |                  |                                 |
| AOZ1342PI-1  |                            |           |                                     |           | Active High    | EPAD SO-8   |                  |                                 |
| AOZ1343AI*   | 1.5 A                      | 0.5A      | 2 A                                 | 0.75 A    | Active Low     | SO-8        |                  |                                 |
| AOZ1343EI*   |                            |           |                                     |           |                | EPAD MSOP-8 |                  |                                 |
| AOZ1343AI-1* |                            |           |                                     |           | Active High    | SO-8        |                  |                                 |
| AOZ1343EI-1* |                            |           |                                     |           |                | EPAD MSOP-8 |                  |                                 |
| AOZ1312AI-1  | 1.5 A                      | None      | 2 A                                 | None      | Active High    | SO-8        |                  |                                 |
| AOZ1312EI-1  |                            |           |                                     |           |                | EPAD MSOP-8 |                  |                                 |
| AOZ1310CI-1  | 0.5 A                      | None      | 0.75 A                              | None      | Active High    | SOT23-5     |                  |                                 |

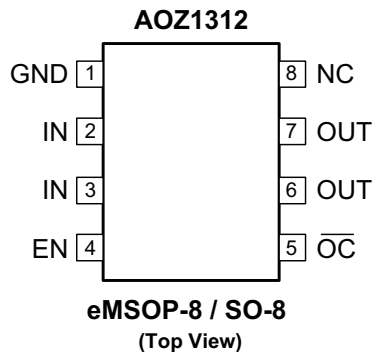
\*Contact factory for availability



AOS Green Products use reduced levels of Halogens, and are also RoHS compliant.

Please visit [www.aosmd.com/web/quality/rohs\\_compliant.jsp](http://www.aosmd.com/web/quality/rohs_compliant.jsp) for additional information.

## Pin Configuration



## Pin Description

| Pin Name        | Pin Number | Pin Function   |
|-----------------|------------|--|
| GND             | 1          | Ground   |
| IN              | 2, 3       | Input voltage  |
| EN              | 4          | Enable input, logic high turns on power switch, IN-OUT |
| $\overline{OC}$ | 5          | Overcurrent, open-drain output, active low, IN-OUT     |
| OUT             | 6, 7       | Power-switch output, IN-OUT                            |
| NC              | 8          | No connection  |

## Absolute Maximum Ratings

Exceeding the Absolute Maximum Ratings may damage the device.

| Parameter                     | Rating            |
|-------------------------------|-------------------|
| Input Voltage ( $V_{IN}$ )    | 6 V               |
| Enable Voltage ( $V_{EN}$ )   | 6 V               |
| Storage Temperature ( $T_S$ ) | -55 °C to +150 °C |
| ESD Rating <sup>(1)</sup>     | 2 kV              |

### Note:

1. Devices are inherently ESD sensitive, handling precautions are required. Human body model is a 100 pF capacitor discharging through a 1.5 k $\Omega$  resistor.

## Recommended Operating Conditions

The device is not guaranteed to operate beyond the Recommended Operating Conditions.

| Parameter                                    | Rating            |
|--|-------------------|
| Input Voltage ( $V_{IN}$ )                   | +2.7 V to +5.5 V  |
| Junction Temperature ( $T_J$ )               | -40 °C to +125 °C |
| Package Thermal Resistance ( $\Theta_{JA}$ ) |                   |
| eMSOP-8                                      | 60 °C/W           |
| SO-8   | 115 °C/W          |

## Electrical Characteristics

$T_A = 25\text{ °C}$ ,  $V_{IN} = V_{EN} = 5.5\text{ V}$ , unless otherwise specified.

| Symbol                 | Parameter                         | Conditions <sup>(3)</sup>   | Min.  | Typ. | Max. | Units         |               |
|------------------------|-----------------------------------|---|---|------|------|---------------|---------------|
| <b>POWER SWITCH</b>    |                                   |   |   |      |      |               |               |
| $R_{DS(ON)}$           | Switch On-Resistance              | $V_{IN} = 5.5\text{ V}$ , $I_{OUT} = 1.5\text{ A}$                                      |   | 70   | 135  | m $\Omega$    |               |
| $t_r$                  | Rise Time, Output                 | $V_{IN} = 5.5\text{ V}$ , $C_L = 1\text{ }\mu\text{F}$ , $R_L = 5\text{ }\Omega$        |   | 0.6  | 1.5  | ms            |               |
|                        |                                   | $V_{IN} = 2.7\text{ V}$ , $C_L = 1\text{ }\mu\text{F}$ , $R_L = 5\text{ }\Omega$        |   | 0.4  | 1    |               |               |
| $t_f$                  | Fall Time, Output                 | $V_{IN} = 5.5\text{ V}$   | 0.05  |      | 0.5  | ms            |               |
|                        |                                   | $V_{IN} = 2.7\text{ V}$   | 0.05  |      | 0.5  |               |               |
|                        | FET Leakage Current               | Out connect to ground,<br>$V_{I(ENx)} = 5.5\text{ V}$ ,<br>or $V_{I(ENx)} = 0\text{ V}$ | $-40\text{ °C} \leq T_J \leq 125\text{ °C}^{(2)}$ |      | 1    | $\mu\text{A}$ |               |
| <b>ENABLE INPUT EN</b> |                                   |   |   |      |      |               |               |
| $V_{IH}$               | High-level Input Voltage          | $2.7\text{ V} \leq V_{IN} \leq 5.5\text{ V}$  | 2.0   |      |      | V             |               |
| $V_{IL}$               | Low-level Input Voltage           | $2.7\text{ V} \leq V_{IN} \leq 5.5\text{ V}$  |   |      | 0.8  | V             |               |
| $I_I$                  | Input Current                     |   | -0.5  |      | -0.5 | $\mu\text{A}$ |               |
| $t_{on}$               | Turn-on Time                      | $C_L = 100\text{ }\mu\text{F}$ , $R_L = 5\text{ }\Omega$                                |   |      | 3    | ms            |               |
| $t_{off}$              | Turn-off Time                     | $C_L = 100\text{ }\mu\text{F}$ , $R_L = 5\text{ }\Omega$                                |   |      | 10   |               |               |
| <b>CURRENT LIMIT</b>   |                                   |   |   |      |      |               |               |
| $I_{OS}$               | Short-circuit Output Current      |   | 1.5   | 2.0  | 2.5  | A             |               |
| $I_{OC\_TRIP}$         | Overcurrent Trip Threshold        |   | 1.6   | 2.3  | 2.7  | A             |               |
| <b>SUPPLY CURRENT</b>  |                                   |   |   |      |      |               |               |
|                        | Supply Current, Low-level Output  | No load on OUT,<br>$V_{I(ENx)} = 5.5\text{ V}$ ,<br>or $V_{I(ENx)} = 0\text{ V}$        | $T_J = 25\text{ °C}$                              |      | 0.5  | 1             | $\mu\text{A}$ |
|                        |                                   |   | $-40\text{ °C} \leq T_J \leq 125\text{ °C}^{(2)}$ |      | 0.5  | 5             |               |
|                        | Supply Current, High-level Output | No load on OUT,<br>$V_{I(ENx)} = 0\text{ V}$ ,<br>or $V_{I(ENx)} = 5.5\text{ V}$        | $T_J = 25\text{ °C}$                              |      | 50   | 70            | $\mu\text{A}$ |
|                        |                                   |   | $-40\text{ °C} \leq T_J \leq 125\text{ °C}^{(2)}$ |      | 50   | 90            |               |
|                        | Reverse Leakage Current           | $V_{I(OUTx)} = 5.5\text{ V}$ , IN = ground  | $T_J = 25\text{ °C}$                              |      | 0.2  | $\mu\text{A}$ |               |

**Electrical Characteristics** (Continued)

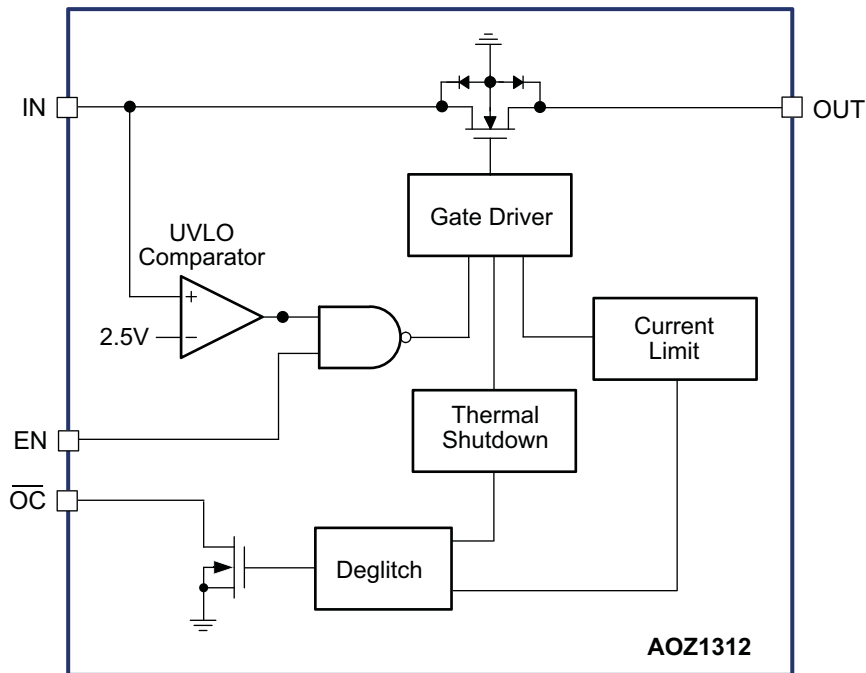
$T_A = 25\text{ }^\circ\text{C}$ ,  $V_{IN} = V_{EN} = 5.5\text{ V}$ , unless otherwise specified.

| Symbol                      | Parameter                        | Conditions <sup>(3)</sup>                  | Min. | Typ. | Max. | Units            |
|-----------------------------|----------------------------------|--|------|------|------|------------------|
| <b>UNDERVOLTAGE LOCKOUT</b> |                                  |  |      |      |      |                  |
|                             | Low-level Voltage, IN            |  | 2    |      | 2.5  | V                |
|                             | Hysteresis, IN                   | $T_J = 25^\circ\text{C}$                   |      | 200  |      | mV               |
| <b>OVERCURRENT OC</b>       |                                  |  |      |      |      |                  |
|                             | Output low Voltage $V_{OL(OCx)}$ | $I_{O(OCx)} = 5\text{ mA}$                 |      |      | 0.4  | V                |
|                             | Off-state Current                | $V_{O(OCx)} = 5\text{ V or } 3.3\text{ V}$ |      |      | 1    | $\mu\text{A}$    |
|                             | OC_L Deglitch                    | OCx assertion or deassertion               | 4    | 8    | 15   | ms               |
| <b>THERMAL SHUTDOWN</b>     |                                  |  |      |      |      |                  |
|                             | Thermal Shutdown Threshold       |  | 135  |      |      | $^\circ\text{C}$ |
|                             | Recovery from Thermal Shutdown   |  | 105  |      |      | $^\circ\text{C}$ |
|                             | Hysteresis                       |  |      | 30   |      | $^\circ\text{C}$ |

**Note:**

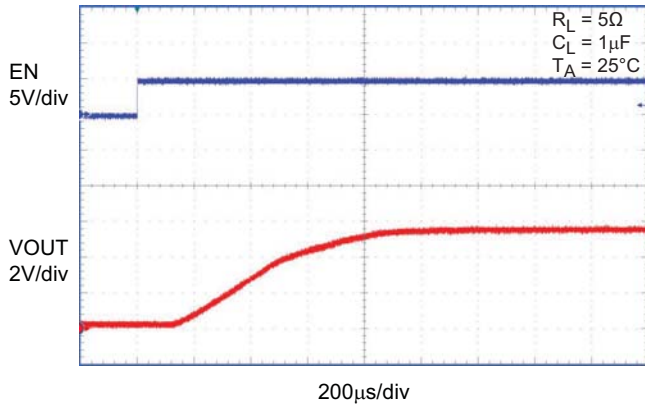
- Parameters are guaranteed by design only and not production tested.
- Pulse testing techniques maintain junction temperature close to ambient temperature; thermal effects must be taken into account separately.

**Functional Block Diagram**

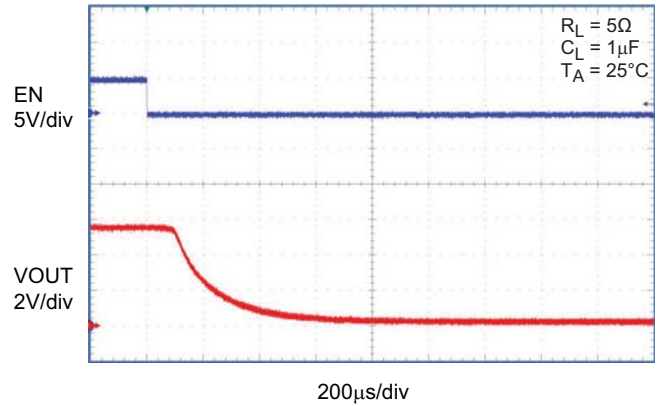


## Functional Characteristics

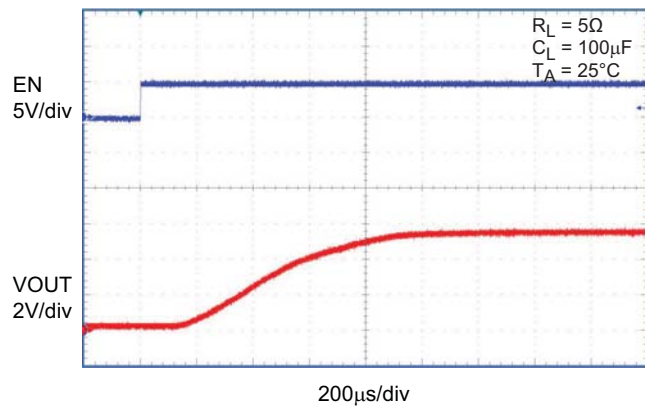
**Figure 1. Turn-On Delay and Rise Time with 1 $\mu$ F Load (Active High)**



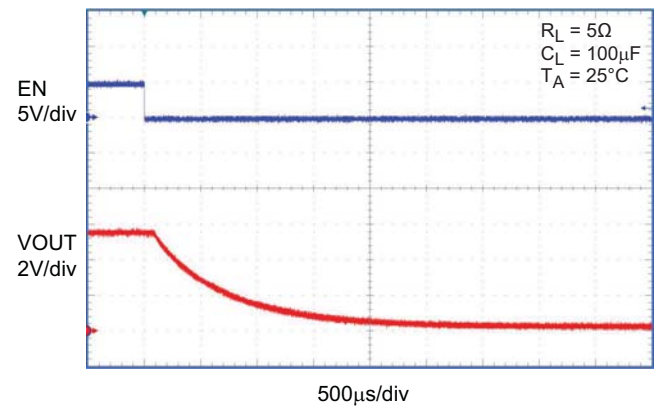
**Figure 2. Turn-Off Delay and Fall Time with 1 $\mu$ F Load (Active High)**



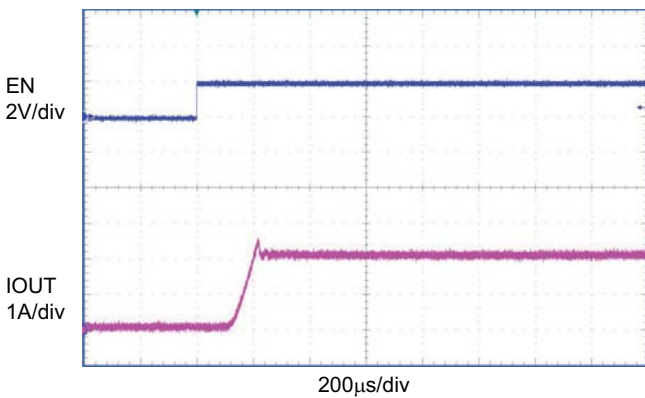
**Figure 3. Turn-On Delay and Rise Time with 100 $\mu$ F Load (Active High)**



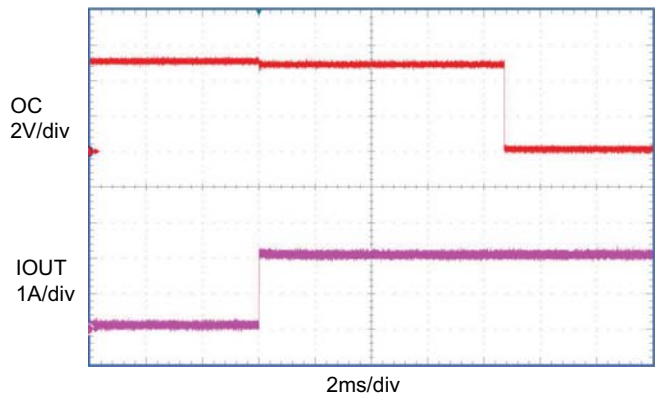
**Figure 4. Turn-Off Delay and Fall Time with 100 $\mu$ F Load (Active High)**



**Figure 5. Short-circuit Current, Device Enable to Short (Active High)**



**Figure 6. 0.6 $\Omega$  Load Connected to Enable to Device (Active High)**



Functional Characteristics (Continued)

Figure 7. Inrush Current with Different Load Capacitance

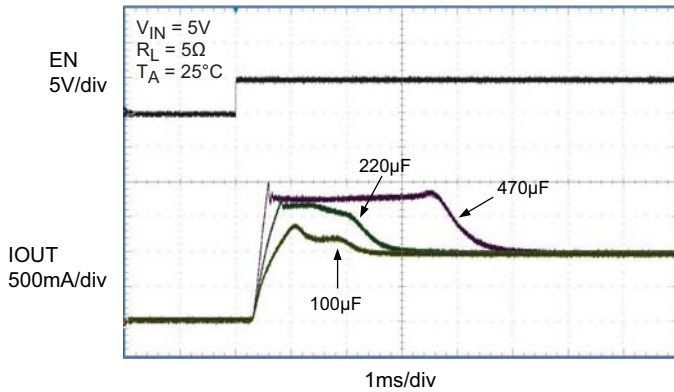
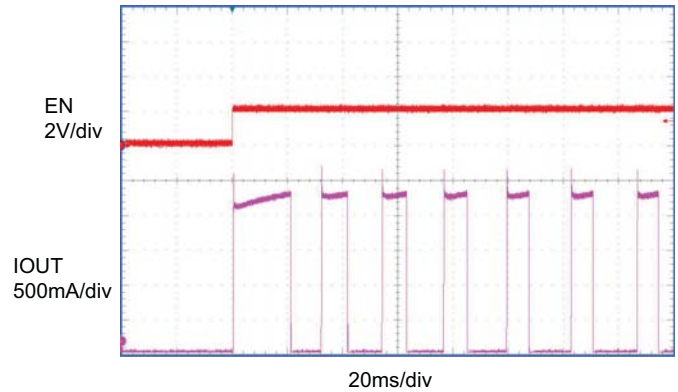


Figure 8. Short Circuit Current Limit



Typical Characteristics

Figure 9. Supply Current, Output Enabled vs. Junction Temperature

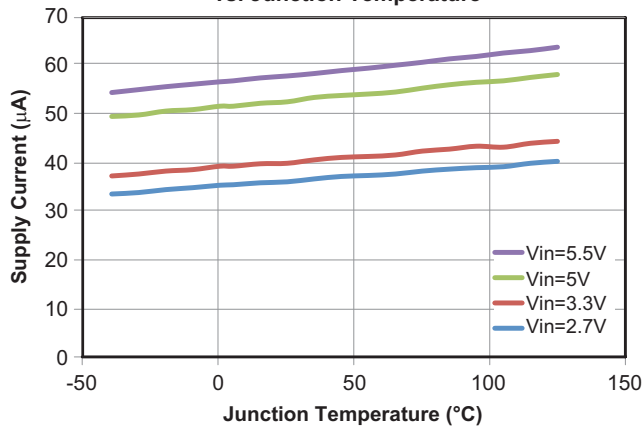


Figure 10. Supply Current, Output Disabled vs. Junction Temperature

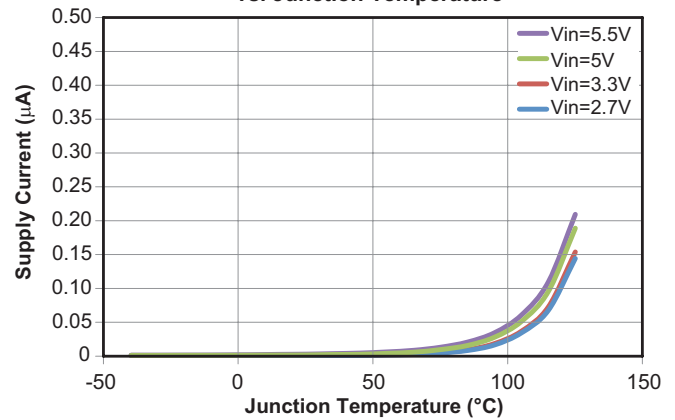


Figure 11. Rds(on) vs. Ambient Temperature

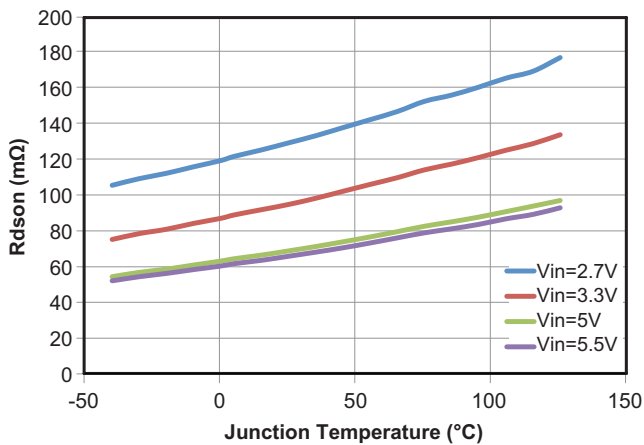
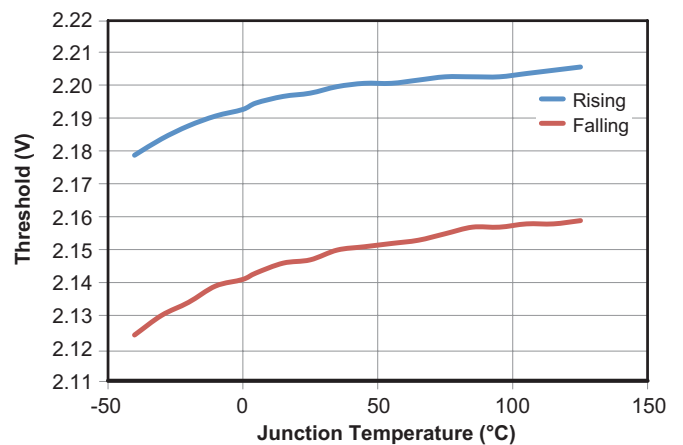


Figure 12. UVLO Threshold vs. Junction Temperature



## Detailed Description

The AOZ1312 is a member of Alpha and Omega Semiconductor's single-channel power-distribution switches family. The AOZ1312 is intended for applications where heavy capacitive loads and short-circuits are likely to be encountered. Gate drive is provided by an internal charge pump designed to control the power-switch rise times and fall times to minimize current surges during switching. The charge pump requires no external components and allows operation from supplies as low as 2.7 V.

### Power Switch

The power switch is a N-channel MOSFET with a low on-state resistance capable of delivering 1 A of continuous current. Configured as a high-side switch, the MOSFET will go into high impedance when disabled. Thus, preventing current flow from OUT to IN and IN to OUT.

### Charge Pump

An internal charge pump supplies power to the circuits and provides the necessary voltage to drive the gate of the MOSFET beyond the source. The charge pump is capable of operating down to a low voltage of 2.7 Volts.

### Driver

The driver controls the voltage on the gate to the power MOSFET switch. This is used to limit the large current surges when the switch is being turned On and Off. Proprietary circuitry controls the rise and fall time of the output voltages.

### Enable

The logic enable disables the power switch, charge pump, gate driver, logic device, and other circuitry to reduce the supply current. When the enable receives a logic high the supply current is reduced to approximately 1  $\mu$ A. The enable input is compatible with both TTL and CMOS logic levels.

### Over-current

The over-current open drain output is asserted (active low) when an over-current condition occurs. The output will remain asserted until the over-current condition is removed. A 15 ms deglitch circuit prevents the over-current from false triggering.

### Thermal Shut-down Protection

When the output load exceeds the current-limit threshold or a short is present, the device limits the output current to a safe level by switching into a constant-current mode, pulling the overcurrent (OC) logic output low.

During current limit or short circuit conditions, the increasing power dissipation in the chip causing the die temperature to rise. When the die temperature reaches a certain level, the thermal shutdown circuitry will shutdown the device. The thermal shutdown will cycle repeatedly until the short circuit condition is resolved.

## Applications Information

### Input Capacitor Selection

The input capacitor prevents large voltage transients from appearing at the input, and provides the instantaneous current needed each time the switch turns on and to limit input voltage drop. The input capacitor also prevents high-frequency noise on the power line from passing through the output of the power side. The choice of the input capacitor is based on its ripple current and voltage ratings rather than its capacitor value. The input capacitor should be located as close to the  $V_{IN}$  pin as possible. A 1  $\mu\text{F}$  and above ceramic cap is recommended. However, higher capacitor values further reduce the voltage drop at the input.

### Output Capacitor Selection

The output capacitor acts in a similar way. A small 0.1  $\mu\text{F}$  capacitor prevents high-frequency noise from going into the system. Also, the output capacitor has to supply enough current for a large load that it may encounter during system transients. This bulk capacitor must be large enough to supply fast transient load in order to prevent the output from dropping.

### Power Dissipation Calculation

Calculate the power dissipation for normal load condition using the following equation:

$$P_D = R_{ON} \times (I_{OUT})^2$$

The worst case power dissipation occurs when the load current hits the current limit due to over-current or short circuit faults. The power dissipation under these conditions can be calculated using the following equation:

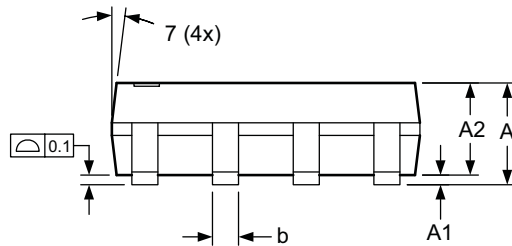
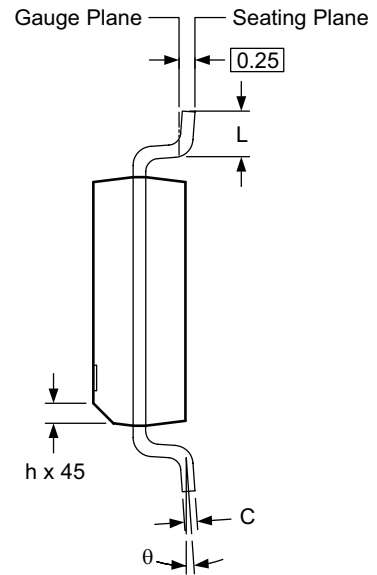
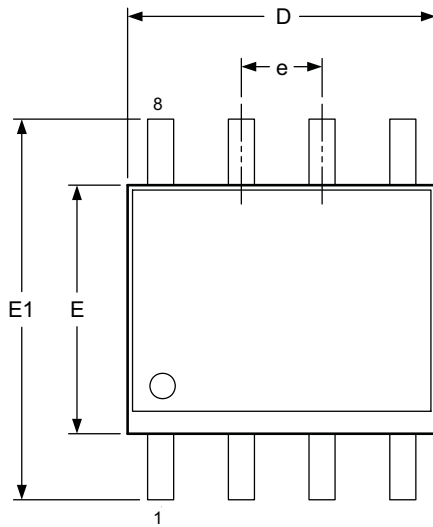
$$P_D = (V_{IN} - V_{OUT}) \times I_{LIMIT}$$

### Layout Guidelines

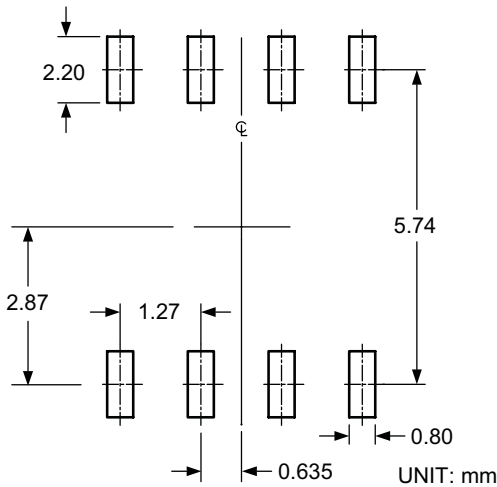
Good PCB layout is important for improving the thermal and overall performance of the AOZ1312. To optimize the switch response time to output short-circuit conditions keep all traces as short as possible to reduce the effect of unwanted parasitic inductance. Place the input and output bypass capacitors as close as possible to the IN and OUT pins. The input and output PCB traces should be as wide as possible for the given PCB space. Use a ground plane to enhance the power dissipation capability of the device.



Package Dimensions, SO-8L



RECOMMENDED LAND PATTERN



Dimensions in millimeters

| Symbols | Min.     | Nom. | Max. |
|---------|----------|------|------|
| A       | 1.35     | 1.65 | 1.75 |
| A1      | 0.10     | —    | 0.25 |
| A2      | 1.25     | 1.50 | 1.65 |
| b       | 0.31     | —    | 0.51 |
| c       | 0.17     | —    | 0.25 |
| D       | 4.80     | 4.90 | 5.00 |
| E       | 3.80     | 3.90 | 4.00 |
| e       | 1.27 BSC |      |      |
| E1      | 5.80     | 6.00 | 6.20 |
| h       | 0.25     | —    | 0.50 |
| L       | 0.40     | —    | 1.27 |
| θ       | 0°       | —    | 8°   |

Dimensions in inches

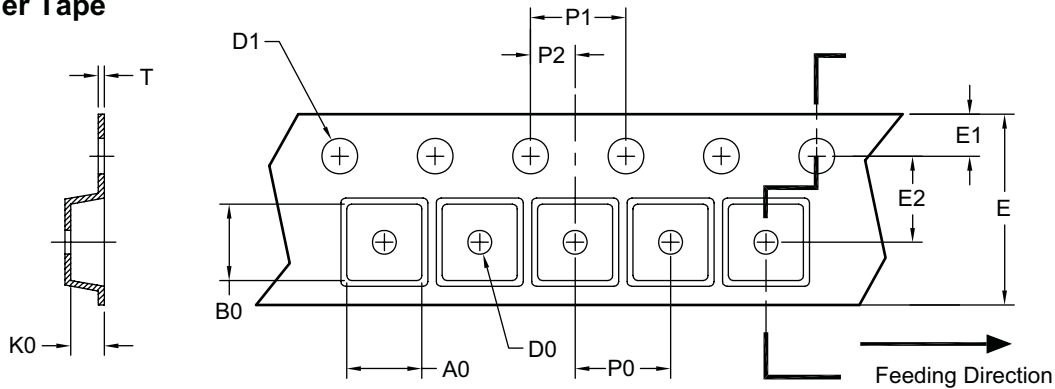
| Symbols | Min.      | Nom.  | Max.  |
|---------|-----------|-------|-------|
| A       | 0.053     | 0.065 | 0.069 |
| A1      | 0.004     | —     | 0.010 |
| A2      | 0.049     | 0.059 | 0.065 |
| b       | 0.012     | —     | 0.020 |
| c       | 0.007     | —     | 0.010 |
| D       | 0.189     | 0.193 | 0.197 |
| E       | 0.150     | 0.154 | 0.157 |
| e       | 0.050 BSC |       |       |
| E1      | 0.228     | 0.236 | 0.244 |
| h       | 0.010     | —     | 0.020 |
| L       | 0.016     | —     | 0.050 |
| θ       | 0°        | —     | 8°    |

Notes:

1. All dimensions are in millimeters.
2. Dimensions are inclusive of plating
3. Package body sizes exclude mold flash and gate burrs. Mold flash at the non-lead sides should be less than 6 mils.
4. Dimension L is measured in gauge plane.
5. Controlling dimension is millimeter, converted inch dimensions are not necessarily exact.

### Tape and Reel Dimensions, SO-8

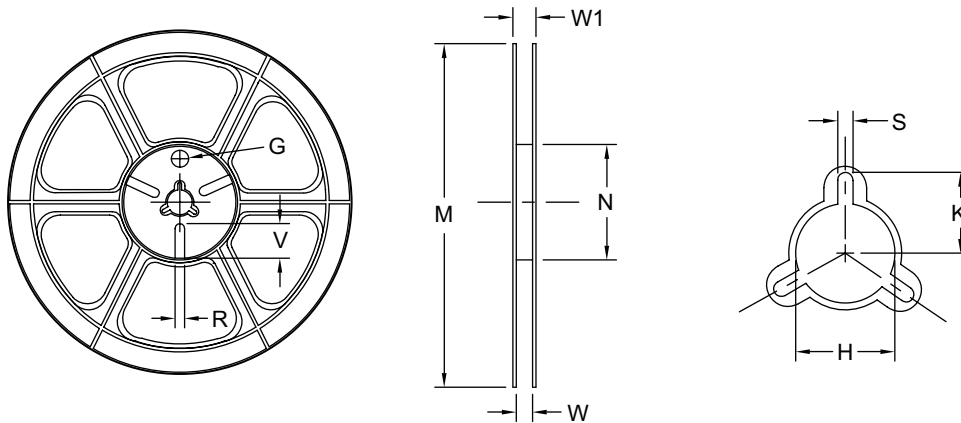
#### Carrier Tape



UNIT: mm

| Package        | A0                 | B0                 | K0                 | D0                 | D1                 | E                   | E1                 | E2                 | P0                 | P1                 | P2                 | T                  |
|----------------|--------------------|--------------------|--------------------|--------------------|--------------------|---------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| SO-8<br>(12mm) | 6.40<br>$\pm 0.10$ | 5.20<br>$\pm 0.10$ | 2.10<br>$\pm 0.10$ | 1.60<br>$\pm 0.10$ | 1.50<br>$\pm 0.10$ | 12.00<br>$\pm 0.10$ | 1.75<br>$\pm 0.10$ | 5.50<br>$\pm 0.10$ | 8.00<br>$\pm 0.10$ | 4.00<br>$\pm 0.10$ | 2.00<br>$\pm 0.10$ | 0.25<br>$\pm 0.10$ |

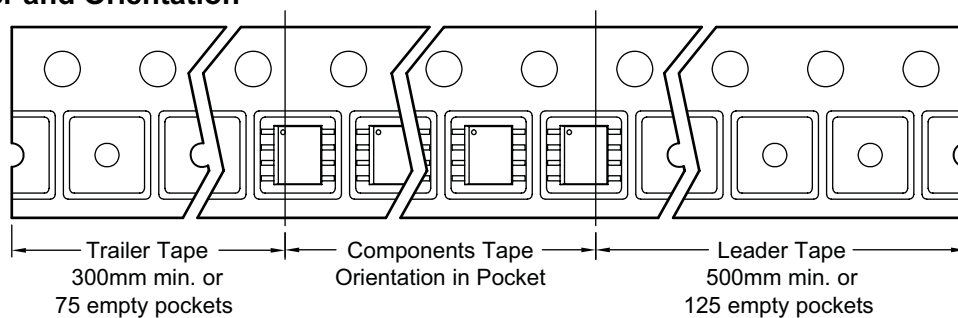
#### Reel



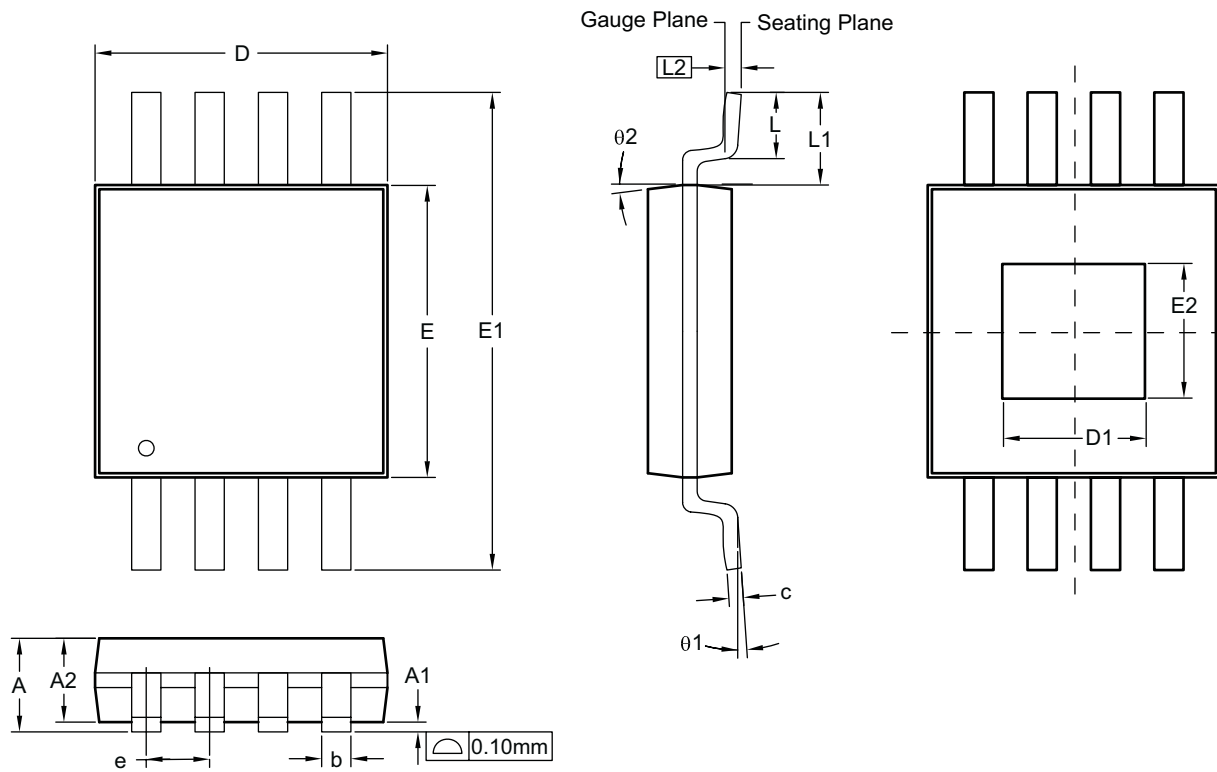
UNIT: mm

| Tape Size | Reel Size  | M                           | N                          | W                   | W1                  | H                             | K     | S                  | G | R | V |
|-----------|------------|-----------------------------|----------------------------|---------------------|---------------------|-------------------------------|-------|--------------------|---|---|---|
| 12mm      | $\phi 330$ | $\phi 330.00$<br>$\pm 0.50$ | $\phi 97.00$<br>$\pm 0.10$ | 13.00<br>$\pm 0.30$ | 17.40<br>$\pm 1.00$ | $\phi 13.00$<br>$+0.50/-0.20$ | 10.60 | 2.00<br>$\pm 0.50$ | — | — | — |

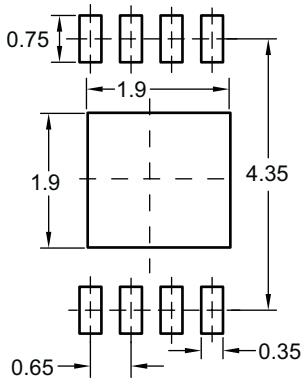
#### Leader/Trailer and Orientation



Package Dimensions, MSOP8\_EP1



RECOMMENDED LAND PATTERN



Dimensions in millimeters

| Symbols | Min.      | Nom. | Max. |
|---------|-----------|------|------|
| A       | 0.81      | 1.02 | 1.12 |
| A1      | 0.05      | —    | 0.15 |
| A2      | 0.76      | 0.86 | 0.97 |
| b       | 0.25      | 0.30 | 0.40 |
| c       | 0.13      | 0.15 | 0.23 |
| D       | 2.90      | 3.00 | 3.10 |
| D1      | 1.55      | —    | 1.8  |
| e       | 0.65 TYP. |      |      |
| E       | 2.90      | 3.00 | 3.10 |
| E1      | 4.70      | 4.90 | 5.10 |
| E2      | 1.3       | —    | 1.8  |
| L       | 0.40      | 0.55 | 0.70 |
| L1      | 0.90      | 0.95 | 1.00 |
| L2      | 0.25 BSC  |      |      |
| theta1  | 0°        | —    | 6°   |
| theta2  | —         | 12°  | —    |

Dimensions in inches

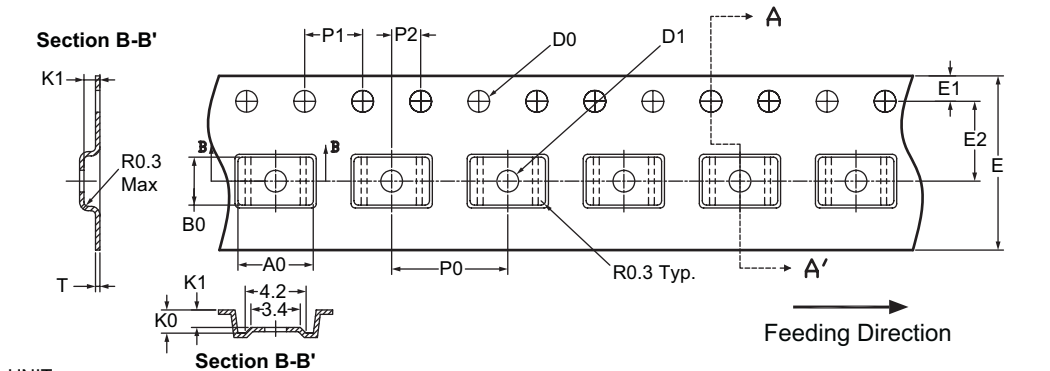
| Symbols | Min.       | Nom.  | Max.  |
|---------|------------|-------|-------|
| A       | 0.032      | 0.040 | 0.044 |
| A1      | 0.002      | —     | 0.006 |
| A2      | 0.030      | 0.034 | 0.038 |
| b       | 0.010      | 0.012 | 0.016 |
| c       | 0.005      | 0.006 | 0.010 |
| D       | 0.116      | 0.118 | 0.120 |
| D1      | 0.06       | —     | 0.07  |
| e       | 0.026 TYP. |       |       |
| E       | 0.116      | 0.118 | 0.120 |
| E1      | 0.185      | 0.192 | 0.20  |
| E2      | 0.05       | —     | 0.07  |
| L       | 0.016      | 0.022 | 0.028 |
| L1      | 0.035      | 0.037 | 0.039 |
| L2      | 0.010 BSC  |       |       |
| theta1  | 0°         | —     | 6°    |
| theta2  | —          | 12°   | —     |

Notes:

1. All dimensions are in millimeters.
2. Dimensions are inclusive of plating.
3. Package body sizes exclude mold flash and gate burrs. Mold flash at the non-lead sides should be less than 6 mils each.
4. Dimension L is measured in gauge plane.
5. Controlling dimension is millimeter, converted inch dimensions are not necessarily exact.

## Tape and Reel Dimensions, MSO8P\_EP1

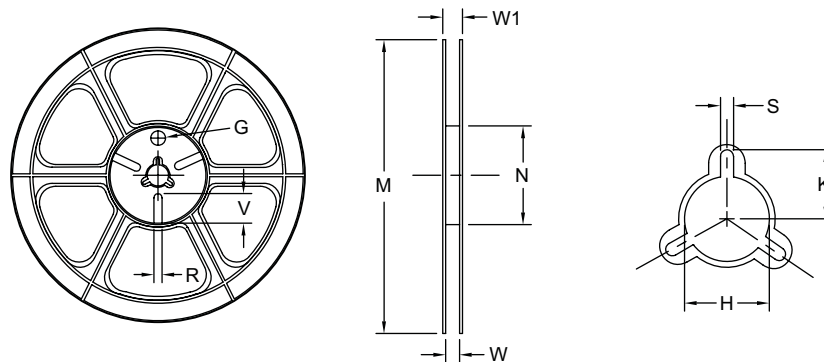
### Carrier Tape



UNIT: mm

| Package | T             | B0            | A0            | K1            | K0            | D0                 | D1            | E            | E1            | E2            | P0            | P1            | P2            |
|---------|---------------|---------------|---------------|---------------|---------------|--------------------|---------------|--------------|---------------|---------------|---------------|---------------|---------------|
| MSOP-8  | 0.30<br>±0.05 | 3.30<br>±0.10 | 5.20<br>±0.10 | 1.20<br>±0.10 | 1.60<br>±0.10 | ø1.50<br>+0.1/-0.0 | ø1.50<br>Min. | 12.0<br>±0.3 | 1.75<br>±0.10 | 5.50<br>±0.05 | 8.00<br>±0.10 | 4.00<br>±0.05 | 2.00<br>±0.05 |

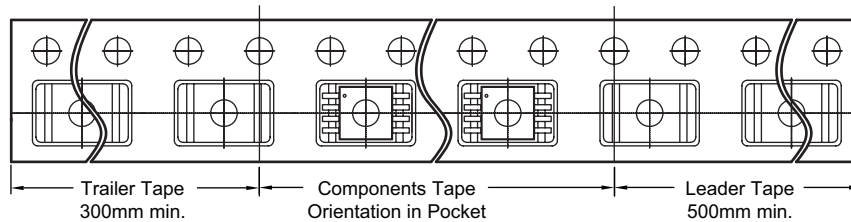
### Reel



UNIT: mm

| Tape Size | Reel Size | M                | N               | W              | W1             | H                     | K     | S             | G | R | V |
|-----------|-----------|------------------|-----------------|----------------|----------------|-----------------------|-------|---------------|---|---|---|
| 12mm      | ø330      | ø330.00<br>±0.50 | ø97.00<br>±0.10 | 13.00<br>±0.30 | 17.40<br>±1.00 | ø13.00<br>+0.50/-0.20 | 10.60 | 2.00<br>±0.50 | — | — | — |

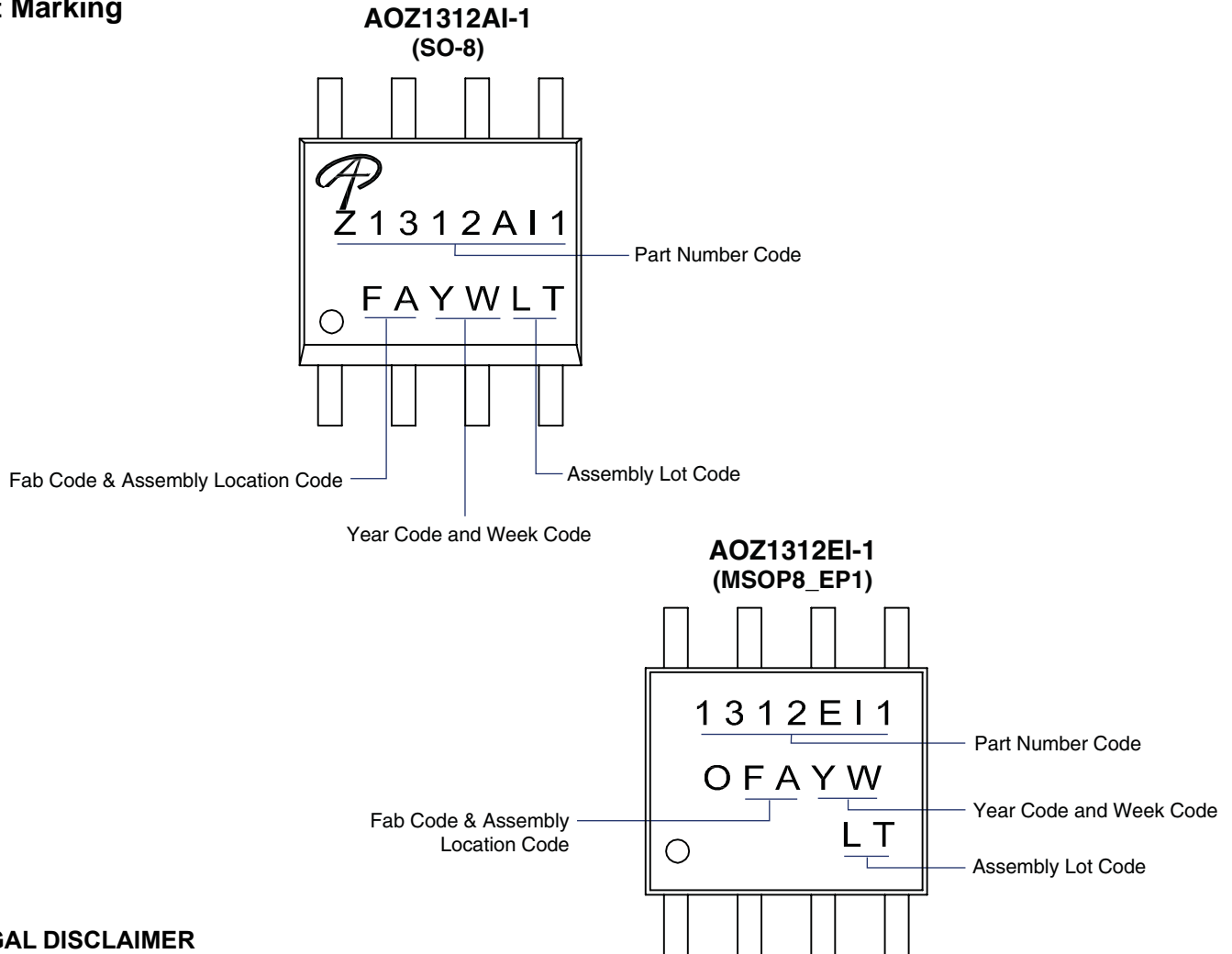
### Leader/Trailer and Orientation



#### Notes:

- 10 sprocket hole pitch cumulative tolerance 0.2.
- Camber not to exceed 1mm in 100mm.
- A0 and B0 measured on a plane 0.3mm above the bottom of the pocket.
- K0 measured from a plane on the inside bottom of the pocket to the top surface of the carrier.
- Pocket position relative to sprocket hole measured as the position of pocket, not pocket hole.
- All dimensions in mm.

**Part Marking**



**LEGAL DISCLAIMER**

Applications or uses as critical components in life support devices or systems are not authorized. AOS does not assume any liability arising out of such applications or uses of its products. AOS reserves the right to make changes to product specifications without notice. It is the responsibility of the customer to evaluate suitability of the product for their intended application. Customer shall comply with applicable legal requirements, including all applicable export control rules, regulations and limitations.

AOS' products are provided subject to AOS' terms and conditions of sale which are set forth at:

[http://www.aosmd.com/terms\\_and\\_conditions\\_of\\_sale](http://www.aosmd.com/terms_and_conditions_of_sale)

**LIFE SUPPORT POLICY**

ALPHA & OMEGA SEMICONDUCTOR PRODUCTS ARE NOT AUTHORIZED FOR USE AS CRITICAL COMPONENTS IN LIFE SUPPORT DEVICES OR SYSTEMS.

As used herein:

1. Life support devices or systems are devices or systems which, (a) are intended for surgical implant into the body or (b) support or sustain life, and (c) whose failure to perform when properly used in accordance with instructions for use provided in the labeling, can be reasonably expected to result in a significant injury of the user.
2. A critical component in 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.