

101.419-06 – including *Taq* polymerase, IFU-01
 101.419-06u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **18S**

Lot-specific information
Olerup SSP[®] HLA-A*36

| | |
|----------------------------------|---|
| Product number: | 101.419-06 – including <i>Taq</i> polymerase 101.419-06u – without <i>Taq</i> polymerase |
| Lot number: | 18S |
| Expiry date: | 2016-May-01 |
| Number of tests: | 6 |
| Number of wells per test: | 7 |
| Storage - pre-aliquoted primers: | dark at -20°C |
| - PCR Master Mix: | -20°C |
| - Adhesive PCR seals | RT |
| - Product Insert | RT |

This Product Description is only valid for Lot No. 18S.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
 HLA-A*36 LOT (04R)**

The HLA-A*36 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®]* HLA-A*36 lot was made (Lot No. 04R).

The HLA-A*36 kit is updated for new alleles to enable separation of:

- Confirmed¹ alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The Lot-specific information for HLA-A*36 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

| Well | 5'-primer | 3'-primer | rationale |
|------|-----------|-----------|--|
| 4 | Modified | - | Modified 5'-primer, for increased yield of HLA-specific PCR product. |

101.419-06 – including *Taq* polymerase, IFU-01
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PRODUCT DESCRIPTION

HLA-A*36 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-A*36:01 to HLA-A*36:05 alleles.

PLATE LAYOUT

Each test consists of 7 PCR reactions in an 8 well cut PCR plate. Well 8 is empty.

| | | | | | | | |
|---|---|---|---|---|---|---|-------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | empty |
|---|---|---|---|---|---|---|-------|

The 8 well cut PCR plate is marked with 'A36' in silver/gray ink.

Well No. 1 is marked with '18S'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are heat-sealed with a PCR-compatible foil.

Please note: When removing each 8 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-A*36 SSP subtypings will be influenced by most A*01 alleles, most A*03 alleles, most A*11 alleles, two A*24 alleles, two A*31 alleles and the A*32:04 allele and allele when present on the other haplotype. In addition, the HLA-B*15:90 allele will be amplified by primer mix 4.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*36 alleles, i.e. **A*36:01 to A*36:05**, recognized by the HLA Nomenclature Committee in July 2013¹ will be amplified by the primers in the HLA-A*36 subtyping kit.

The HLA-A*36 kit enables separation of the confirmed HLA-A*36 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-A*36 alleles is listed below.

The HLA-A*36 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

¹HLA-A alleles listed on the IMGT/HLA web page 2013-July-25, release 3.13.1, www.ebi.ac.uk/imgt/hla.

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ALLELE CONFIRMATION STATUS

| Allele | Status ¹ |
|----------------|---------------------|
| A*36:01 | Confirmed |
| A*36:02 | Unconfirmed |
| A*36:03 | Confirmed |
| A*36:04 | Unconfirmed |
| A*36:05 | Unconfirmed |

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2013-July-25, release 3.13.1, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 5 alleles generate 5 amplification patterns that can be combined in 15 homozygous and heterozygous combinations. 2 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

++-----+ *36:01, *36:05 = *36:05, *36:05

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Lot-specific information
SPECIFICITY TABLE

HLA-A*36 SSP subtyping

Specificities and sizes of the PCR products of the 7 primer mixes used for HLA-A*36 SSP subtyping

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified HLA-A*36 alleles | Other amplified HLA-A alleles ³ |
|----------------------|--|-----------------------------------|----------------------------|---|
| 1⁴ | 75 bp | 800 bp | *36:01-36:03, 36:05 | *01:14 ^w , 31:62 |
| 2 | 225 bp | 1070 bp | *36:01, 36:04-36:05 | *01:01:01:01-01:02, 01:04N, 01:07-01:11N, 01:13-01:14, 01:16N-01:18N, 01:21-01:33, 01:35-01:52N, 01:54-01:62, 01:64, 01:67-01:72, 01:74-01:97, 01:99-01:126, 01:128-01:129, 01:131-01:135, 01:137-01:138, 03:18, 03:135, 11:94, 11:112 |
| 3 | 235 bp | 800 bp | *36:02 | *03:01:01:01-03:01:29, 03:01:31-03:01:34, 03:01:36-03:04:03, 03:07-03:09, 03:11N-03:17:02, 03:19-03:39, 03:41, 03:43-03:74, 03:76-03:94, 03:96-03:97, 03:99-03:104, 03:106-03:121, 03:123:01-03:134, 03:136-03:166, 03:168N-03:174, 11:130, 32:04 |
| 4⁵ | 230 bp | 1070 bp | *36:03 | *01:73, 01:89, 24:22, 24:160, B*15:90 |
| 5 | 235 bp | 1070 bp | *36:04 | *01:72, 11:01:01-11:01:20, 11:01:22-11:01:43, 11:01:45-11:01:48, 11:01:50-11:03, 11:05-11:14, 11:16-11:25, 11:29-11:33:02, 11:36-11:37, 11:40-11:49, 11:51-11:52Q, 11:54-11:89, 11:91-11:93, 11:95-11:100, 11:102-11:117, 11:119:01-11:129, 11:131-11:138, 11:140-11:142, 11:144-11:150 |

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| | | | | |
|----------------------|--------|---------|--------------|--|
| 6⁴ | 85 bp | 1070 bp | *36:01-36:05 | *11:01:01 ^w -11:01:15 ^w , 11:01:17 ^w -11:01:48 ^w , 11:01:50 ^w -11:02:04 ^w , 11:04 ^w - 11:07 ^w , 11:09 ^w -11:13 ^w , 11:15:01 ^w -11:19 ^w , 11:21N ^w - 11:24:02 ^w , 11:26 ^w , 11:29 ^w - 11:30 ^w , 11:32 ^w -11:34 ^w , 11:36 ^w -11:37 ^w , 11:40 ^w - 11:49 ^w , 11:51 ^w -11:52Q ^w , 11:54 ^w -11:59 ^w , 11:61 ^w - 11:93 ^w , 11:95 ^w -11:150 ^w , 31:24 ^w , 31:62 |
| 7⁴ | 110 bp | 1070 bp | *36:05 | |

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-A*36 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits the respective lengths of the HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A*36 subtyping.

In addition, well number 3 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

³Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*36 alleles will be amplified by primer mixes 1 to 6. In addition, the HLA-B*15:90 allele will be amplified by primer mix 4.

⁴HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁵Primer mix 4 has a tendency to giving rise to primer oligomer formation, and may also have tendencies of unspecific amplifications.

^w, might be weakly amplified.

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Lot-specific information

| INTERPRETATION TABLE | | | | | | | |
|---|-------------|-------------|------------|-------------|-------------|-------------|-------------|
| HLA-A*36 SSP subtyping | | | | | | | |
| Amplification patterns of the A*36:01 to A*36:05 alleles | | | | | | | |
| | Well | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Length of spec. | 75 | 225 | 235 | 230 | 235 | 85 | 110 |
| PCR product | | | | | | | |
| Length of int. | 800 | 1070 | 800 | 1070 | 1070 | 1070 | 1070 |
| pos. control¹ | | | | | | | |
| 5'-primer² | 527 | 363 | 363 | 355 | 363 | 527 | 363 |
| | 5' -TgC 3' | 5' -ATA 3' | 5' -ATA 3' | 5' -CCC 3' | 5' -ATA 3' | 5' -TgC 3' | 5' -ATA 3' |
| 3'-primer³ | 559 | 545 | 555 | 545 | 559 | 570 | 430 |
| | 5' -CgT 3' | 5' -AgA 3' | 5' -CCA 3' | 5' -AgA 3' | 5' -CCg 3' | 5' -CAC 3' | 5' -gCA 3' |
| | | 545 | | 545 | | | |
| | | 5' -AgA 3' | | 5' -AgA 3' | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| HLA-A allele⁴ | | | | | | | |
| *36:01 | 1 | 2 | | | | 6 | |
| *36:02 | 1 | | 3 | | | 6 | |
| *36:03 | 1 | | | 4 | | 6 | |
| *36:04 | | 2 | | | 5 | 6 | |
| *36:05 | 1 | 2 | | | | 6 | 7 |
| *01:01:01:01-01:02, 01:04N, 01:07-01:11N, 01:13, 01:16N-01:18N, 01:21-01:33, 01:35-01:52N, 01:54-01:62, 01:64, 01:67-01:71, 01:74-01:88, 01:90-01:97, 01:99-01:126, 01:128-01:129, 01:131-01:135, 01:137-01:138, 03:18, 03:135, 11:94 | | 2 | | | | | |
| *01:14 | w | 2 | | | | | |
| *01:72 | | 2 | | | 5 | | |
| *01:73, 24:22, 24:160, B*15:90 | | | | 4 | | | |
| *01:89 | | 2 | | 4 | | | |
| *03:01:01:01-03:01:29, 03:01:31-03:01:34, 03:01:36-03:04:03, 03:07-03:09, 03:11N-03:17:02, 03:19-03:39, 03:41, 03:43-03:74, 03:76-03:94, 03:96-03:97, 03:99-03:104, 03:106-03:121, 03:123:01-03:134, 03:136-03:166, 03:168N-03:174, 32:04 | | | 3 | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

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| Length of spec. | 75 | 225 | 235 | 230 | 235 | 85 | 110 |
|--|----------|----------|----------|-----|----------|----------|-----|
| PCR product | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| *11:01:01-11:01:15, 11:01:17-11:01:20, 11:01:22-11:01:43, 11:01:45-11:01:48, 11:01:50-11:02:04, 11:05-11:07, 11:09- 11:13, 11:16-11:19, 11:21N-11:24:02, 11:29-11:30, 11:32-11:33:02, 11:36-11:37, 11:40-11:49, 11:51-11:52Q, 11:54-11:59, 11:61-11:89, 11:91-11:93, 11:95-11:100, 11:102-11:111, 11:113-11:117, 11:119:01- 11:129, 11:131-11:138, 11:140-11:142, 11:144-11:150 | | | | | 5 | w | |
| *11:01:16, 11:03, 11:08, 11:14, 11:20, 11:25, 11:31, 11:60 | | | | | 5 | | |
| *11:01:21, 11:01:44, 11:04, 11:15:01- 11:15:02, 11:26, 11:34, 11:90, 11:101, 11:118, 11:139, 11:143, 31:24 | | | | | | w | |
| *11:112 | | 2 | | | 5 | w | |
| *11:130 | | | 3 | | | w | |
| *31:62 | 1 | | | | | 6 | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A*36 subtyping. In addition, well number 3 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in 3rd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

⁴HLA-A*36 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.13.1, July 2013.

'w', might be weakly amplified.

101.419-06 – including *Taq* polymerase, IFU-01
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Lot-specific information

| CELL LINE VALIDATION SHEET | | | | | | | | | | | |
|----------------------------|-----------------|--|--------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| HLA-A*36 SSP subtyping kit | | | | | | | | | | | |
| | | | | Prod. No.: | Well | | | | | | |
| | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| | | | | | 200963501 | 201316902 | 200963503 | 201316904 | 200963505 | 200963506 | 201181707 |
| | IHWC cell line | | A* | | | | | | | | |
| 1 | 9001 SA | | *24:02 | | - | - | - | - | - | - | - |
| 2 | 9280 LK707 | | *02:01 | | - | - | - | - | - | - | - |
| 3 | 9011 E4181324 | | *01:01 | | - | + | - | - | - | - | - |
| 4 | 9275 GU373 | | *30:01 | | - | - | - | - | - | - | - |
| 5 | 9009 KAS011 | | *01:01 | | - | + | - | - | - | - | - |
| 6 | 9353 SM | | *02:01 | *26:03 | - | - | - | - | - | - | - |
| 7 | 9020 QBL | | *26:01 | | - | - | - | - | - | - | - |
| 8 | 9025 DEU | | *31:01 | | - | - | - | - | - | - | - |
| 9 | 9026 YAR | | *26:01 | | - | - | - | - | - | - | - |
| 10 | 9107 LKT3 | | *24:02 | | - | - | - | - | - | - | - |
| 11 | 9051 PITOUT | | *29:02 | | - | - | - | - | - | - | - |
| 12 | 9052 DBB | | *02:01 | | - | - | - | - | - | - | - |
| 13 | 9004 JESTHOM | | *02:01 | | - | - | - | - | - | - | - |
| 14 | 9071 OLGA | | *31:01 | | - | - | - | - | - | - | - |
| 15 | 9075 DKB | | *24:02 | | - | - | - | - | - | - | - |
| 16 | 9037 SWEIG007 | | *29:02 | | - | - | - | - | - | - | - |
| 17 | 9282 CTM3953540 | | *03:01 | *80:01 | - | - | + | - | - | - | - |
| 18 | 9257 32367 | | *33:03 | *74:01 | - | - | - | - | - | - | - |
| 19 | 9038 BM16 | | *02:01 | | - | - | - | - | - | - | - |
| 20 | 9059 SLE005 | | *02:01 | | - | - | - | - | - | - | - |
| 21 | 9064 AMALA | | *02:17 | | - | - | - | - | - | - | - |
| 22 | 9056 KOSE | | *02:01 | | - | - | - | - | - | - | - |
| 23 | 9124 IHL | | *02:01 | *34:01 | - | - | - | - | - | - | - |
| 24 | 9035 JBUSH | | *32:01 | | - | - | - | - | - | - | - |
| 25 | 9049 IBW9 | | *33:01 | | - | - | - | - | - | - | - |
| 26 | 9285 WT49 | | *02:05 | | - | - | - | - | - | - | - |
| 27 | 9191 CH1007 | | *24:10 | *29:01 | - | - | - | - | - | - | - |
| 28 | 9320 BEL5GB | | *02:01 | *29:02 | - | - | - | - | - | - | - |
| 29 | 9050 MOU | | *29:02 | | - | - | - | - | - | - | - |
| 30 | 9021 RSH | | *30:01 | *68:02 | - | - | - | - | - | - | - |
| 31 | 9019 DUCAF | | *30:02 | | - | - | - | - | - | - | - |
| 32 | 9297 HAG | | *02:01 | | - | - | - | - | - | - | - |
| 33 | 9098 MT14B | | *31:01 | | - | - | - | - | - | - | - |
| 34 | 9104 DHIF | | *31:01 | | - | - | - | - | - | - | - |
| 35 | 9302 SSTO | | *32:01 | | - | - | - | - | - | - | - |
| 36 | 9024 KT17 | | *02:06 | *11:01 | - | - | - | - | + | W | - |
| 37 | 9065 HHKB | | *03:01 | | - | - | + | - | - | - | - |
| 38 | 9099 LZL | | *02:17 | | - | - | - | - | - | - | - |
| 39 | 9315 CML | | *01:01 | *03:01 | - | + | + | - | - | - | - |
| 40 | 9134 WHONP199 | | *02:07 | *30:01 | - | - | - | - | - | - | - |
| 41 | 9055 H0301 | | *03:01 | | - | - | + | - | - | - | - |
| 42 | 9066 TAB089 | | *02:07 | | - | - | - | - | - | - | - |
| 43 | 9076 T7526 | | *02:06 | *02:07 | - | - | - | - | - | - | - |
| 44 | 9057 TEM | | *66:01 | | - | - | - | - | - | - | - |
| 45 | 9239 SHJO | | *23:01 | *24:02 | - | - | - | - | - | - | - |
| 46 | 9013 SCHU | | *03:01 | | - | - | + | - | - | - | - |
| 47 | 9045 TUBO | | *02:16 | *03:01 | - | - | + | - | - | - | - |
| 48 | 9303 TER-ND | | *02:01 | *11:01 | - | - | - | - | + | W | - |

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CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*36 SSP

| | |
|---------------------------|---|
| Product number: | 101.419-06 – including <i>Taq</i> polymerase 101.419-06u – without <i>Taq</i> polymerase |
| Lot number: | 18S |
| Expiry date: | 2016-May-01 |
| Number of tests: | 6 |
| Number of wells per test: | 7 |

Well specifications:

| Well No. | Production No. |
|----------|----------------|
| 1 | 2009-635-01 |
| 2 | 2013-169-02 |
| 3 | 2009-635-03 |
| 4 | 2013-169-04 |
| 5 | 2009-635-05 |
| 6 | 2009-635-06 |
| 7 | 2011-817-07 |

The specificity of each primer solution of the kit has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solution 7 was available. The specificities of the 5'-primer in primer solutions 7 was tested by separately adding one additional 3'-primer, the 3'-primer was not possible to test.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2013-November-08

Approved by:

Production Quality Control

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Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*36
Product number: 101.419-06/06u
Lot number: 18S

Intended use: HLA-A*36 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2013-November-08

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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Lot-specific information

ADDRESSES:

Manufacturer:

Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-717 88 27

Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: <http://www.olerup-ssp.com>

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com

Web page: <http://www.olerup.com>

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1

Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.