

#01 P.1

From:
Sent: Wednesday, November 07, 2007 9:51 AM
To:
Subject: FW: MSDS Response

MSDS info from AgaMatrix. Let me know if this meets the cut.

Product & Supplier Management
 McKesson Medical Surgical
 8741 Landmark Road
 Richmond, VA 23228

804.264.7601 Fax

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From: Mike Vidmar [mailto:MVidmar@agamatrix.com]
Sent: Wednesday, November 07, 2007 9:37 AM
To:
Subject: RE: MSDS Response

Hi.

This is what was sent as an explanation to me.

An MSDS is a Material Safety Data Sheet. The MSDS is designed to provide both **workers** and **emergency personnel** with the proper procedures for handling or working with a **particular substance**. MSDS's include information such as physical data (melting point, boiling point, flash point etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment and what to do in the event of a leak or chemical. MSDS's are **not meant for consumers**. MSDS's are meant for: 1) employees who may be occupationally exposed to a hazard at work, b) employers who need to know the proper methods for handling, storage, disposal, etc. and 3) emergency responders such as fire fighters, hazardous material crews, emergency medical technicians, and emergency room personnel. An MSDS reflects the hazards of working with the "material" (acids, reagents, epoxies, RTV, and a million other substances) in an **occupational fashion**. MSDS's are not required to be submitted for anything we buy or make (meters, strips, control solution, lancing devices, lancets, etc).

Mike Vidmar
 Director of Managed Care & US Distribution
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** see attached for item
 information **

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From:**Sent:** Wednesday, November 07, 2007 9:27 AM**To:** Mike Vidmar**Subject:** RE: MSDS Response

Mike, Thanks for your response. While it seemed your email did not get to Kristy, it did. She copied me and the 510(k) situation is resolved.

I will send a copy of the MSDS response to her this morning, but am not entirely sure it will be accepted. Our corporate view is that OSHA requires MSDS sheets to be available for customers.

From a commercial view, this will not stop products from being added to the system. However, it will confuse the team.

What would be ideal would be a formal statement from your regulatory/QA person explaining why MSDS sheets are not necessary.

I am in the office today if you want to discuss. Thanks.

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McKesson Medical Surgical
8741 Landmark Road
Richmond, VA 23228

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From: Mike Vidmar [mailto:MVidmar@agamatrix.com]**Sent:** Wednesday, November 07, 2007 8:58 AM**To:****Subject:** MSDS Response

Hi

This was the MSDS response from our QA – “MSDS’s are not required to be submitted for anything we buy or make (meters, strips, control solution, lancing devices, lancets, etc).”

I copied Christy on the 510K email but it bounced back to me.

Please let me know if you need any additional information.

Sincerely,

Mike Vidmar

11/7/2007

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| | A | B | C | D | E |
|----|--------|----------|------------|-----------|--------------------------------|
| 1 | Item # | Mfg Abbv | Catalog # | MSDS Code | Description |
| 2 | 638782 | AGAMAT | 8000-01317 | 01 | MONITOR, BLD GLUC WAVESENSE KE |
| 3 | 638783 | AGAMAT | 8000-01328 | 01 | TEST STRIP, BLD GLUC WAVESENSE |
| 4 | 638784 | AGAMAT | 8000-01333 | 01 | CONTROL, NORMAL WAVESENSE KEYN |
| 5 | 638785 | AGAMAT | 8000-01971 | 01 | LANCET, WAVESENSE KEYNOTE 33G |
| 6 | 638786 | AGAMAT | 8000-02011 | 01 | CONTROL, HIGH WAVESENSE KEYNOT |
| 7 | 638787 | AGAMAT | 8000-02265 | 01 | TEST STRIP, BLD GLUC WAVESENSE |
| 8 | 693965 | AGAMAT | 8000-02649 | 01 | MONITOR KIT, BLD GLUC STRT WAV |
| 9 | 693966 | AGAMAT | 8000-03329 | 01 | TEST STRIP, BLD GLUC WAVESENSE |
| 10 | 693967 | AGAMAT | 8000-03337 | 01 | TEST STRIP, BLD GLUC WAVESENSE |
| 11 | 693968 | AGAMAT | 8000-03383 | 01 | METER, BLD GLUC WAVESENSE PRES |
| 12 | 703006 | AGAMAT | 8000-03384 | 01 | METER, ONLY BLD GLUC KEYNOTE P |