



Modern Challenges for Lactose & Derivatives

IDF Symposium - Moscow

Andy Williams – May 2007



Dairy for life

Introduction

- Lactose has become a milk solid of note but lactose intolerance is the first thing found on Google
- Many applications and potentially more diverse uses
- Where are some of those applications – how does one prioritise various uses or growth options
- Can we really get a fix on actual production and uses
- Why are so few papers or texts on lactose published (relative to fat or protein)
- The stock feed applications are worthy options or are they

Modern Challenges for Lactose Production

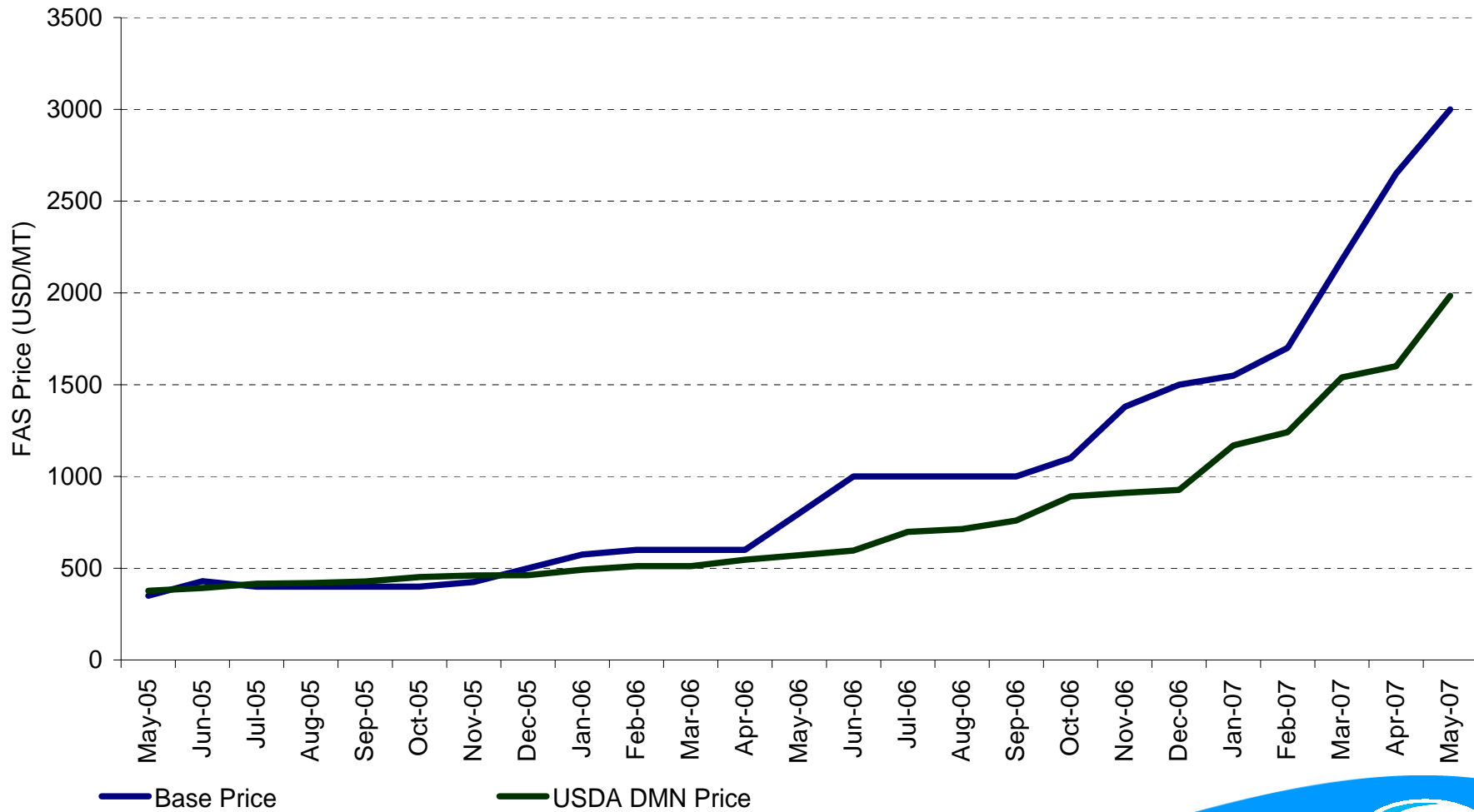
- Pharmaceutical
- Ethanol & Stock Feed
- Challenges



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There has been a stepwise change in lactose prices

Lactose Market Price



The increase in the lactose price has been driven by a number of factors

- Drivers of Lactose Price
 - **Higher dairy commodity prices** which are expected to continue driven by factors such as Australia drought, small milk growth in US etc
 - **Increasing substitution of other dairy components** (e.g. cheaper feed/filler source driven by a large extent by SMP price and availability)
 - **Strong demand for carbohydrates for alternative fuels** (particularly soy and corn – both also used as raw materials for fuel production)
 - **Double digit growth of infant formula in Asia** (requires whey and lactose solids).
 - **EU standardisation** to commence in January 2008 if it has not already.

Five year price for lactose is \$2000 to \$2500 USD/MT

- Five year price \$2000 to 2500 USD/MT – big call but a challenge
- Nothing in short term to change current state
- The macro-trend
 - Increasing cheese production in EU and US at the expense of SMP/butter
 - The extent of the price decline is a question of solids balance and the major factor driving the lactose long term will be the availability and pricing of SMP
 - Increase in Permeate Powders
 - Demand for Nutritional standard lactose e.g. EB/10gm, Es
 - > Uses higher grade lactose otherwise destined

Lactose Market Update

- Pricing



- Ethanol & Stock Feed

- Challenges

Where is lactose used - general?

- Tablets and capsules
 - Lactose is used in approximately 2/3 of all pharmaceutical tablets primarily as a filler to bulk out the tablet.
 - It is nearly ideal for this as it is soluble in water, non-hygroscopic, almost tasteless, chemically fairly inert and it compresses into robust tablets.
 - Approximately 100,000 metric tonnes per year is used for this purpose, with a growth rate of about 4% per year.
 - The use of lactose in tablets and capsules is well understood.



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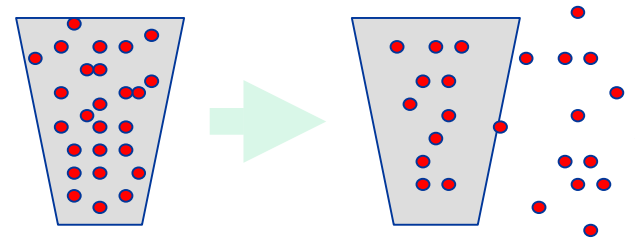
Where is lactose used – hi tech?

- Dry Powder Inhalers (DPI)
 - Treatment for asthma and chronic obstructive pulmonary disease is frequently administered locally to the lungs and airways by inhalation.
 - The Montreal Protocol banning the use of CFC propellants lead to a rapid increase in the number of other inhalation devices.
 - Lactose is used as a “carrier” in many DPI’s to overcome some of the disadvantages of micronised active drug
 - Approximately 500 metric tonnes per year is used in this application, mostly as “customised” grades.
 - The scientific and regulatory world for lactose in DPI is changing!

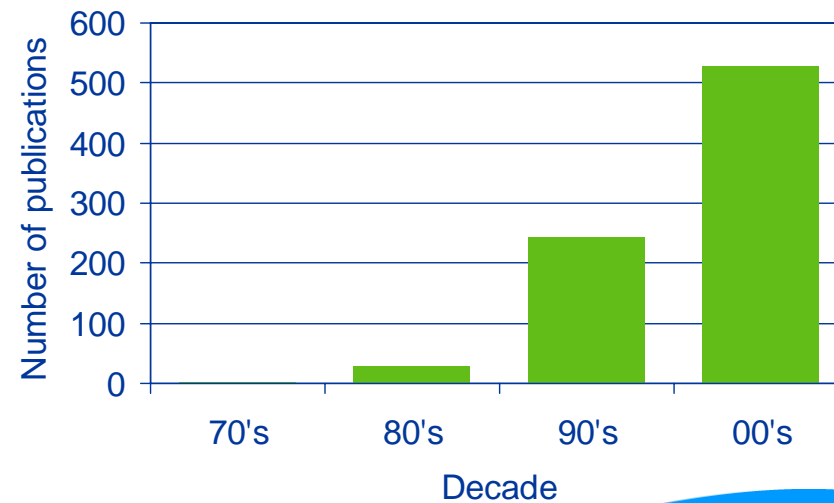


Increase in Scientific Attention

- Micronised drug (<math><5\mu\text{m}</math>) is evenly mixed with a coarse carrier lactose (typically 50 to 100 $\mu\text{m}</math>) to improve handling properties.$
- During inhalation the drug has to be “stripped” from the lactose so that it can be inhaled into the airways and lungs.
- Historically, the lactose was controlled for particle size distribution, but there is increasing focus on manipulation and control of surface properties.
- The publication rate has increased dramatically in the last 2 decades



DPI publications in PubMed



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Increase in Regulatory Attention

- Draft USP-NF monographs “Lactose Monohydrate for Inhalation” and “Anhydrous Lactose for Inhalation” are expected to be published soon.
- These monographs are expected to propose tightening of some existing USP-NF specifications for lactose, and the inclusion of some additional requirements.
- Expectations of tightened specifications
 - Absorbance at 400nm
 - Specific optical rotation
 - Karl Fischer water content
- Expectations of added specifications
 - Protein content
 - Amorphous content
 - β -lactose content
 - Related sugar content
 - Extra micro tests
- Can producers meet the expected changes?

Where might the attention lead?

- Lactose for use in DPI's today is typically standard pharmaceutical lactose with tight particle size specifications.
- Increasing academic attention on surface properties (for example characterisation of surface energy by inverse gas chromatography, measurement of detachment force of drug by atomic force microscopy) can lead to a need to control surface properties. This may be achieved through (another) crystallisation step, specifically for inhalation lactose.
- Changes in the regulatory monographs, if adopted, may also lead to a need to change the lactose manufacturing process, again specifically for lactose for inhalation.
- Thus for dry powder inhalation, lactose may be transformed from a high volume / low cost excipient into a highly specialised / low-volume / high cost excipient made by only a very few producers worldwide.



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Lactose Market Update

- Pricing
- Pharmaceutical

- Challenges

Ethanol

- Limited use of lactose solids – 3 countries using whey?
 - Recent announcement of Müller to start (DIN April)
- Expensive feedstock c.f. plant sources
- Low yield – disposal streams for slops
- Has eco efficiency credits and perceptions of being “better”
- Hazardous handling and contrary to dairy manufacture procedures
- Relatively low returns

Stock Feed

- Mother liquor stream from the lactose process has a valuable contribution
- Contains a number of micro elements for development opportunities
- Will increase milk growth in dairy cows more effectively than most supplements (Dexcel NZ)
- Also provides growth for beef animals (University of NSW, Au)
- Available for “double cropping”
- Largely an untapped source especially on low yield plants
 - I’m sure some of the Technologies speakers will address this

Lactose Market Update

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Challenges

- Does the scientific community involve itself with the market dynamics of lactose?
- Is there too much reliance on engineering firms
- How much research actually benefits production efficiencies
 - Caking was a major issue up until 5 years ago but benefited from science based application e.g. NIZO, Massey University et al
 - Mould is not so prevalent
 - Becoming “hi tech” rather than a problem as a waste
- Will what we hear today and tomorrow provide un thought of efficiencies or uses.

Summary

- Over the past years significant progress in utilisation has occurred –
 - Sometimes out of necessity
 - Other times out of demand
- Functional and operational frustrations have diminished
- Scientific study has intensified – jury out whether it is enough
- Will lactose production increase – undoubtedly
 - But so will other derivatives such as permeate powder
 - Albeit small volumes but Pharmaceutical will put lactose into the mainstream
 - Nutritional demand for quality can exceed Pharmaceutical



Thank you